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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: ROTH et al.	Group Art Unit: 3732
Serial No.: 09/978,002	Confirmation No.: 3810
Filed: October 17, 2001	Examiner: Eduardo C. Robert
For: BONE FIXATION SYSTEM	Attorney Docket No.: 8932-266-999

DISCLOSURE OF LITIGATION PURSUANT TO MPEP 2001.06(c)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to MPEP 2001.06(c), applicant hereby brings to the attention of the Examiner information regarding the existence of litigation involving the subject matter of the present application.

One or more claims of the present application encompass a device known as the "Trochanteric Fixation Nail System" (the "Synthes TFN"), presently being produced by assignee Synthes (U.S.A.). As set forth in the attached complaint, the Synthes TFN has become the subject of litigation in the United States District Court for the Western District of Tennessee, Civil Action No. 02-CV-2873. Specifically, the plaintiff in that action, Smith & Nephew, Inc., has alleged that the Synthes TFN infringes certain claims of U.S. Patent No. 5,312,406 to Brumfield, and U.S. Patent No. 5,167,663 to Brumfield. (The asserted Brumfield patents were cited by applicant in the Information Disclosure Statement of January 2, 2002.) Defendant Synthes (U.S.A.) has counterclaimed that the asserted patents are invalid, unenforceable and not infringed. (*See* complaint and answer, attached as Ex. A.)

The plaintiff in this action, Smith & Nephew, previously asserted the Brumfield '406 patent and the '663 patent against another intramedullary nail known as the

Howmedica Gamma Nail. That prior litigation was terminated by a settlement agreement between the parties. A brochure describing the Gamma Nail is attached hereto for the Examiner's reference. (*See* Gamma Locking Nail brochure, attached as Ex. B.)

It is requested that the Examiner make the present notification of record in the application. No fee is believed to be due. However, should any fees be required, please charge such fees to Jones Day deposit account No. 50-3013.

Respectfully submitted,

Date: August 24, 2004

Brian M. Rothery (Reg. No. 35,340)
By: Howard I. Shin (Reg. No. 47,082)
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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

SMITH & NEPHEW, INC.,

Plaintiff,

v.

SYNTHES-STRATEC, INC. and SYNTHES USA, INC.,

Defendants.

02-2873 Ma RRE

Civil Action No. _____

COMPLAINT

Plaintiff, Smith & Nephew, Inc. ("Smith & Nephew") files this complaint against Defendants Synthes-Stratec, Inc. and Synthes USA, Inc. and alleges as follows:

PARTIES

1. Plaintiff, Smith & Nephew, is a Delaware corporation having its principal place of business in Memphis, Tennessee. Smith & Nephew is in the business of designing, manufacturing, and selling, among other products, orthopedic implants and orthopedic instruments.

2. Defendant, Synthes-Stratec, Inc., is a foreign corporation having its principal place of business and a manufacturing facility in the United States at 1301 Goshen Parkway, West Chester, Pennsylvania. Upon information and belief, Synthes-Stratec, Inc. is in the business of designing, importing, manufacturing, distributing and/or selling, among other products, orthopedic implants and orthopedic intramedullary nails in

interstate commerce, and is a direct competitor of Plaintiff Smith & Nephew. Upon information and belief, Synthes-Stratec, Inc. has at least two offices located in Tennessee at 2070 Sunset Drive, Germantown, Tennessee, 38138 and 8935 Chaffin Lane, Chattanooga, Tennessee 37421.

3. Defendant Synthes USA, Inc., is a Delaware corporation having its principal place of business and a manufacturing facility at 1690 Russell Road, Paoli, Pennsylvania. Synthes USA, Inc. has an additional manufacturing facility at 1101 Synthes Avenue, Monument, Colorado. Synthes USA Inc. is in the business of designing, manufacturing, and selling, among other products, orthopedic implants and orthopedic intramedullary nails in interstate commerce, and is a direct competitor of Plaintiff Smith & Nephew. Upon information and belief, Synthes USA, Inc. has at least two offices located in Tennessee at 2070 Sunset Drive, Germantown, Tennessee, 38138 and 8935 Chaffin Lane, Chattanooga, Tennessee 37421.

JURISDICTION AND VENUE

4. This complaint arises under the Patent Act, 35 United States Code § 1, *et seq*. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

5. Upon information and belief, Synthes-Stratec, Inc. and Synthes USA, Inc. are licensed to conduct business in Tennessee, and actually conduct business in Tennessee and in this judicial district on a regular basis. Upon information and belief, Synthes-Stratec, Inc. and Synthes USA, Inc. conduct business in this jurisdiction by offering to sell and by selling infringing intramedullary nails and other devices to

customers located in this judicial district. Accordingly, this Court has personal jurisdiction over Synthes-Stratec, Inc. and Synthes USA, Inc. under T.C.A. 20-2-202, *et seq.* Venue in this district is proper under 28 U.S.C. §§ 1391(b)(c) and (d) as well as 1400(b).

COUNT ONE: INFRINGEMENT OF U.S. PATENT NO. 5,312,406

6. Plaintiff Smith & Nephew incorporates the allegations in paragraphs 1-5 inclusive, as though fully set forth herein.

7. On May 17, 1994, U.S. Patent No. 5,312,406 (the " '406 patent"), entitled "Method Of Treating An Intertrochanteric Fracture," was duly and legally issued. Smith & Nephew owns an undivided interest in the '406 patent by virtue of an assignment from the named inventor, David L. Brumfield. Smith & Nephew or its predecessor-in-interest, Smith & Nephew Richards, Inc., have owned an undivided interest since the date of issuance of the '406 patent.

8. On information and belief, Defendants Synthes-Stratec, Inc. and Synthes USA, Inc. are infringing the '406 patent by making, using, offering to sell and selling the Synthes TFN intramedullary nail covered by one or more of the method claims of the '406 patent. On information and belief, Defendants Synthes-Stratec, Inc. and Synthes USA, Inc. have developed and manufactured the Synthes TFN intramedullary nail, at least in part, at Defendants' facilities in Paoli, Pennsylvania and Monument, Colorado.

9. Further, on information and belief, Defendants Synthes-Stratec, Inc. and Synthes USA, Inc. have sold and are selling the TFN intramedullary nail along with

instructions and training for its use and surgical insertion. Synthes-Stratec, Inc. and Synthes USA, Inc. have committed and will continue to commit these and other acts that constitute inducement to infringe and contributory infringement of the '406 patent.

10. These actions have been undertaken by Defendants Synthes-Stratec, Inc. and Synthes USA, Inc. with knowledge of the '406 patent and such actions constitute willful infringement of the '406 patent rights.

11. Smith & Nephew has been and will continue to be damaged by the infringement of Defendants Synthes-Stratec, Inc. and Synthes USA, Inc. resulting in irreparable injury unless such infringement is enjoined by this Court.

COUNT TWO: INFRINGEMENT OF U.S. PATENT NO. 5,167,663

12. Plaintiff Smith & Nephew incorporates the allegations of paragraphs 1-11 inclusive, as though fully set forth herein.

13. On December 1, 1991, U.S. Patent No. 5, 167,663 (the " '663 patent"), entitled "Femoral Fracture Device," was duly and legally issued to Smith & Nephew. Smith & Nephew owns an undivided interest in the '663 patent by virtue of an assignment from the named inventor, David L. Brumfield. Smith & Nephew or its predecessor-in-interest, Smith & Nephew Richards, Inc., has owned an undivided interest since the date of issuance of the '663 patent.

14. On information and belief, Synthes-Stratec, Inc. and Synthes USA, Inc. are infringing the '663 patent by making, using, offering to sell, and selling the Synthes TFN intramedullary nail covered by one or more claims of the '663 patent. On information

and belief, Defendants Synthes-Stratec, Inc. and Synthes USA, Inc. have developed and manufactured the Synthes TFN intramedullary nail, at least in part, at Defendants' facilities in Paoli, Pennsylvania and Monument, Colorado.

15. Further, on information and belief, Defendants Synthes-Stratec, Inc. and Synthes, Inc. have sold and are selling the Synthes TFN intramedullary nail along with instructions and training for its use and surgical insertion. Synthes-Stratec, Inc. and Synthes USA, Inc. have committed and will continue to commit these and other acts that constitute inducement to infringe and contributory infringement of the '663 patent.

16. These actions by Defendants Synthes-Stratec, Inc. and Synthes USA, Inc. have been undertaken with knowledge of the '663 patent and such actions constitute willful infringement of Smith & Nephew's patent rights.

17. Smith & Nephew has been and will continue to be damaged by the infringement of Synthes-Stratec, Inc. and Synthes USA, Inc. resulting in irreparable injury unless such infringement is enjoined by this Court.

WHEREFORE, Smith & Nephew prays that this Court enter judgment in its favor and against Synthes-Stratec, Inc. and Synthes USA, Inc., as follows:

A. Adjudging that Synthes-Stratec, Inc. and Synthes USA, Inc. have infringed one or more claims of U.S. Patent No. 5,312,406, and that such infringement has been willful and deliberate;

B. Entering a preliminary and permanent injunction, enjoining Synthes-Stratec, Inc. and Synthes USA Inc. from continued infringement of U.S. Patent No. 5,312,406;

C. Adjudging that Synthes-Stratec, Inc. and Synthes USA, Inc. have infringed one or more claims of U.S. Patent No. 5,167,663 and that such infringement has been willful and deliberate;

D. Entering a preliminary and permanent injunction, enjoining Synthes-Stratec, Inc. and Synthes USA, Inc. from continued infringement of U.S. Patent No. 5,167,663;

E. Adjudging this to be an exceptional case pursuant to 35 U.S.C. § 285, and awarding Smith & Nephew its attorneys' fees in this action; and

F. Granting such further relief as the Court deems just and proper.

Respectfully submitted,

Mark Vorder-Bruegge, Jr. (6389)
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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

FILED BY AGT D.C.
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Robert R. Di Trolio
CLERK U.S. DIST. CT.
W.D. OF TN. MEMPHIS

SMITH & NEPHEW, INC.,
1450 Brooks Road
Memphis, TN 38116,

Plaintiff,

v.

SYNTHES U.S.A.
A Pennsylvania Partnership
1690 Russell Road
Paoli, PA 19301-1262,

SYNTHES-STRATEC, INC.,
A Delaware Corporation
1690 Russell Road
Paoli, PA 19301-1262,

SYNTHES INC.,
A Delaware Corporation
1690 Russell Road
Paoli, PA 19301-1262,

and

SYNTHES NORTH AMERICA, INC.,
A Delaware Corporation
1690 Russell Road
Paoli, PA 19301-1262,

Defendants.

Civil Action No. 02-2873

Judge Samuel H. Mays

FIRST AMENDED COMPLAINT

Plaintiff, Smith & Nephew, Inc. ("Smith & Nephew") files this First Amended Complaint against Defendants Synthes USA, Synthes-Stratec, Inc., Synthes Inc., and Synthes North America, Inc. (collectively "Defendants"), and alleges as follows:

PARTIES

1. Smith & Nephew is a Delaware corporation having its principal place of business in Memphis, Tennessee. Smith & Nephew is in the business of designing, manufacturing, and selling, among other products, orthopedic implants and orthopedic instruments.

2. Upon information and belief, Defendant Synthes USA is a Pennsylvania partnership with its principal place of business and headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301. Further, upon information and belief, Defendant Synthes USA has two general partners, Defendant Synthes, Inc. and Defendant Synthes North America, Inc. In the original complaint filed on or about November 13, 2002, Smith & Nephew intended to sue the partnership, Synthes USA, but instead sued and misnamed one of the general partners, Synthes Inc. Further, Defendant Synthes USA operates as a subsidiary to its parent corporation Defendant Synthes-Stratec, Inc, which owns 100% of both Defendants Synthes North America, Inc. and Synthes Inc. Defendant Synthes USA is in the business of designing, manufacturing, and selling, among other products, orthopedic implants and orthopedic intramedullary nails and instructions for their use in interstate commerce and in Tennessee, and is a direct competitor of Smith & Nephew. Upon information and belief, Defendant Synthes USA has at least two offices located in Tennessee at 2070 Sunset Drive, Germantown, Tennessee, 38138 and 8935 Chaffin Lane, Chattanooga, Tennessee 37421.

3. Defendant, Synthes-Stratec, Inc., is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301. Robert S. Douse is listed with the Pennsylvania Secretary of State as the Chief Executive Officer of Defendant Synthes-Stratec, Inc. Upon information and belief, Defendant Synthes-Stratec, Inc. owns 100% of the stock in Defendant Synthes North America, Inc. and Defendant Synthes, Inc. and operates as the parent corporation to Synthes USA. Further, upon information and belief,

Defendant Synthes-Stratec, Inc., by and through its ownership and management of Defendant Synthes North America, Inc. and Defendant Synthes, Inc. and as the parent company to Synthes USA, is in the business of designing, importing, manufacturing, distributing and/or selling, among other products, orthopedic implants and orthopedic intramedullary nails and instructions for their use in interstate commerce and in the State of Tennessee, and is a direct competitor of Smith & Nephew.

4. Defendant Synthes Inc. is a Delaware corporation having its principal place of business and a manufacturing facility at 1690 Russell Road, Paoli, Pennsylvania. Robert S. Douse is listed with the Pennsylvania Secretary of State as the Chief Executive Officer of Defendant Synthes, Inc. Upon information and belief, Defendant Synthes Inc. was formerly Synthes USA Ltd. Inc. and is now wholly owned and managed by Defendant Synthes-Stratec Inc. On information and belief, Defendant Synthes, Inc. owns, through a general partnership with Defendant Synthes North America, 100% of Defendant Synthes USA. Further, upon information and belief, Defendant Synthes, Inc. shares 100% of the management responsibility for Defendant Synthes USA with Defendant Synthes North America, Inc. Upon information and belief, Defendant Synthes, Inc., by and through its ownership and management of Defendant Synthes USA as a general partner, is in the business of designing, importing, manufacturing, distributing and/or selling, among other products, orthopedic implants and orthopedic intramedullary nails and instructions for their use in interstate commerce and in the State of Tennessee, and is a direct competitor of Smith & Nephew.

5. Defendant Synthes North America, Inc., is a Delaware corporation having its principal place of business and a manufacturing facility at 1690 Russell Road, Paoli, Pennsylvania. Robert S. Douse is listed with the Pennsylvania Department of State as the Chief

Executive Officer of Synthes, Inc. Upon information and belief, Defendant Synthes North America, Inc. owns, through a general partnership with Defendant Synthes, Inc., 100% of Defendant Synthes USA. Further, upon information and belief, Defendant Synthes North America, Inc. shares 100% of the management responsibility for Defendant Synthes USA with the Defendant Synthes, Inc. On information and belief, Defendant Synthes North America, Inc., by and through its ownership and management of Defendant Synthes USA as a general partner, is in the business of designing, importing, manufacturing, distributing and/or selling, among other products, orthopedic implants and orthopedic intramedullary nails and instructions for their use in interstate commerce and in the State of Tennessee, and is a direct competitor of Plaintiff Smith & Nephew.

JURISDICTION AND VENUE

6. This complaint arises under the Patent Act, 35 United States Code § 1, *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

7. Synthes USA conducts business in Tennessee and is therefore subject to personal jurisdiction pursuant to T.C.A. 20-2-202, *et seq.*

8. Upon information and belief, Defendant Synthes, Inc. and Defendant Synthes North America, Inc., as general partners to Synthes USA, by and through their ownership, management, affiliation and control of Defendant Synthes USA, conduct business in Tennessee and in this judicial district on a regular basis. Upon information and belief, Defendant Synthes-Stratec, Inc., by and through its ownership, management affiliation and control over Defendants Synthes North America, Inc., Synthes Inc., and Synthes USA, conducts business in Tennessee and in this judicial district on a regular basis. Upon information and belief, Defendant Synthes-Stratec, Inc., Defendant Synthes, Inc. and Defendant Synthes North America, Inc. by and

through their ownership, management, affiliation and control of Defendant Synthes USA, conduct business in Tennessee by offering to sell and by selling infringing intramedullary nails and other devices nails and instructions for their use to customers located in this judicial district. Accordingly, this Court has personal jurisdiction over Defendant Synthes-Stratec, Inc., Defendant Synthes, Inc., Defendant Synthes North America, Inc., and Defendant Synthes USA, under T.C.A. 20-2-202, *et seq.*

9. Venue in this district is proper under 28 U.S.C. §§ 1391(b)(c) and (d) and 1400(b).

COUNT ONE: INFRINGEMENT OF U.S. PATENT NO. 5,312,406

10. Smith & Nephew incorporates the allegations in paragraphs 1-9 inclusive, as though fully set forth herein.

11. On May 17, 1994, U.S. Patent No. 5,312,406 (the " '406 patent"), entitled "Method Of Treating An Intertrochanteric Fracture," was duly and legally issued. Smith & Nephew owns an undivided interest in the '406 patent by virtue of an assignment from the named inventor, David L. Brumfield. Smith & Nephew or its predecessor-in-interest, Smith & Nephew Richards, Inc., have owned an undivided interest since the date of issuance of the '406 patent.

12. On information and belief, Defendants are infringing the '406 patent by making, using, offering to sell and selling the Synthes TFN intramedullary nail with instructions and training for its use and surgical insertion covered by one or more of the method claims of the '406 patent. Defendants have committed and will continue to commit these and other acts that constitute infringement, inducement to infringe and contributory infringement of the '406 patent.

13. Further, on information and belief, Defendants have sold and are selling the TFN intramedullary nail along with instructions and training for its use and surgical insertion. Defendant Synthes USA is making, using, offering to sell and selling the infringing product. Upon information and belief, Defendants Synthes North America, Inc. and Synthes Inc. are liable for the activities of Synthes USA as general partners and as an alter ego, and are also themselves committing acts of direct infringement, contributory infringement, and inducement to infringe in violation of the Patent Laws. Upon information and belief, Defendant Synthes-Stratec, Inc. is liable for the activity of Synthes USA, Synthes North America, Inc. and Synthes Inc. as an alter ego of these Defendant entities, and is also itself committing acts of direct infringement, contributory infringement, and inducement to infringe in violation of the Patent Laws. Defendants have committed and will continue to commit these and other acts that constitute infringement, inducement to infringe and contributory infringement of the '406 patent.

14. These actions have been undertaken by Defendants with knowledge of the '406 patent and such actions constitute willful infringement of Smith & Nephew's patent rights.

15. Smith & Nephew has been and will continue to be damaged by the infringement of Defendants resulting in irreparable injury unless such infringement is enjoined by this Court.

COUNT TWO: INFRINGEMENT OF U.S. PATENT NO. 5,167,663

16. Plaintiff Smith & Nephew incorporates the allegations of paragraphs 1-15 inclusive, as though fully set forth herein.

17. On December 1, 1991, U.S. Patent No. 5, 167,663 (the " '663 patent"), entitled "Femoral Fracture Device," was duly and legally issued to Smith & Nephew. Smith & Nephew owns an undivided interest in the '663 patent by virtue of an assignment from named inventor,

David L. Brumfield. Smith & Nephew or its predecessor-in-interest, Smith & Nephew Richards, Inc., has owned an undivided interest since the date of issuance of the '663 patent.

17. On information and belief, Defendants are infringing the '663 patent by making, using, offering to sell, and selling the Synthes TFN intramedullary nail covered by one or more claims of the '663 patent.

18. Upon information and belief, Defendant Synthes USA is making, using, offering to sell and selling the infringing product. Upon information and belief, Defendants Synthes North America, Inc. and Synthes Inc. are liable for the activities of Synthes USA as general partners and as an alter ego, and are also themselves committing acts of direct infringement, contributory infringement, and inducement to infringe in violation of the Patent Laws. Upon information and belief, Defendant Synthes-Stratec, Inc. is liable for the activity of Synthes USA, Synthes North America, Inc. and Synthes Inc. as an alter ego of these Defendant entities, and is also itself committing acts of direct infringement, contributory infringement, and inducement to infringe in violation of the Patent Laws.

19. These actions by Defendants have been undertaken with knowledge of the '663 patent and such actions constitute willful infringement of Smith & Nephew's patent rights.

20. Smith & Nephew has been and will continue to be damaged by the infringement of Defendants resulting in irreparable injury unless such infringement is enjoined by this Court.

WHEREFORE, Smith & Nephew prays that this Court enter judgment in its favor and against Defendants Synthes USA, Synthes-Stratec, Inc., Synthes Inc., and Synthes North America, Inc., as follows:

A. Adjudging that Defendants Synthes-Stratec, Inc., Synthes Inc., Synthes North America, Inc., and Synthes USA, have infringed one or more claims of U.S. Patent No. 5,312,406, and that such infringement has been willful and deliberate;

B. Entering a preliminary and permanent injunction enjoining Defendants Synthes-Stratec, Inc., Synthes Inc., Synthes North America, Inc., and Synthes USA from continued infringement of U.S. Patent No. 5,312,406;

C. Adjudging that Defendants Synthes-Stratec, Inc., Synthes Inc., Synthes North America, Inc., and Synthes USA have infringed one or more claims of U.S. Patent No. 5,167,663, and that such infringement has been willful and deliberate;

D. Entering a preliminary and permanent injunction enjoining Defendants Synthes-Stratec, Inc., Synthes Inc., Synthes North America, Inc., and Synthes USA from continued infringement of U.S. Patent No. 5,167,663;

E. Adjudging this to be an exceptional case pursuant to 35 U.S.C. § 285, and awarding Smith & Nephew its attorneys' fees in this action; and

F. Granting such further relief as the Court deems just and proper.

Respectfully,

WYATT, TARRANT & COMBS, LLP

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ATTORNEYS FOR PLAINTIFF
SMITH & NEPHEW, INC.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing FIRST AMENDED COMPLAINT was duly served on the original defendants in this action by First Class U.S. Mail, on January 21, 2003, addressed to the following:

James E. Conley, Jr.
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Johnson & Mitchell, PLLC
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Mark Vorder-Bruegge, Jr.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE

SMITH & NEPHEW, INC., Plaintiff, v. SYNTHES (U.S.A.), SYNTHES-STRATEC, INC., SYNTHES, INC. and SYNTHES NORTH AMERICA, INC. Defendants.	Civil Action No. 02-CV-2873 Judge Samuel H. Mays, Jr.

SYNTHES (U.S.A.)'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to Rule 12 of the Federal Rules of Civil Procedure and the applicable case law interpreting that rule, Defendants Synthes-Stratec, Inc., Synthes, Inc., and Synthes North America, Inc. ("Corporate Defendants") hereby reserve their right to answer on their own behalf pending the Court's resolution of the Defendants' pending Motion to Dismiss and Motion to Transfer, both filed on February 20, 2003 in the present action.

Defendant Synthes (U.S.A.), for its answer to plaintiff's First Amended Complaint states as follows:

PARTIES

1. Defendant Synthes (U.S.A.) has insufficient knowledge or information to form a belief as to the allegations of paragraph 1 of the First Amended Complaint, and, accordingly, denies the same.

2. Defendant Synthes (U.S.A.) has insufficient knowledge or information to form a belief as to plaintiff's intent to sue Synthes (U.S.A.) on or about November 13, 2002; and otherwise denies the remaining allegations of paragraph 2 of the First Amended Complaint,

except Synthes (U.S.A.) admits that it is a Pennsylvania partnership in the business of developing, manufacturing, and selling orthopedic implants and intramedullary nails in the United States on a nationwide basis; that its principal place of business and headquarters is at 1690 Russell Road, Paoli, Pennsylvania 19301, and that it has two general partners, Synthes, Inc. and Synthes North America, Inc. and that Synthes-Stratec, Inc. owns 100% of the shares of Synthes North America, Inc. and 100% of the shares of Synthes, Inc.

3. Defendant, Synthes (U.S.A.) denies the allegations set forth in paragraph 3 of the First Amended Complaint, except that it admits that Synthes-Stratec, Inc. is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes-Stratec, Inc. owns 100% of the stock of Synthes, Inc. and Synthes North America, Inc.

4. Defendant, Synthes (U.S.A.) denies the allegations set forth in paragraph 4 of the First Amended Complaint, except that it admits that Synthes, Inc. is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes, Inc. is a 60% general partner of Synthes (U.S.A.).

5. Defendant, Synthes (U.S.A.) denies the allegations set forth in paragraph 5 of the First Amended Complaint, except that it admits that Synthes North America, Inc. is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes North America, Inc. is a 40% general partner of Synthes (U.S.A.).

JURISDICTION AND VENUE

6. Synthes (U.S.A.) admits the allegations set forth in paragraph 6 of the First Amended Complaint.

7. Synthes (U.S.A.) denies the allegations set forth in paragraph 7 of the First Amended Complaint, except that it admits that it is subject to personal jurisdiction in Tennessee.

8. Synthes (U.S.A.) denies the allegations set forth in paragraph 8 of the First Amended Complaint.

9. Synthes (U.S.A.) denies the allegations set forth in paragraph 9 of the First Amended Complaint, except that Synthes (U.S.A.) admits that venue in this district is proper as to Synthes (U.S.A.)

COUNT ONE: INFRINGEMENT OF U.S. PATENT NO. 5,312,406

10. Synthes (U.S.A.) realleges and incorporates by reference paragraphs 1-9 inclusive above as if fully set forth herein in response to the allegations of paragraph 10 of the First Amended Complaint.

11. Synthes (U.S.A.) has insufficient knowledge and information to form a belief as to the allegations set forth in paragraph 11 of the First Amended Complaint, and, therefore, denies the allegations set forth therein, except admits that U.S. Patent No. 5,312,406 ("the '406 patent") was issued on May 17, 1994.

12. Synthes (U.S.A.) denies the allegations of paragraph 12 of the First Amended Complaint.

13. Synthes (U.S.A.) denies the allegations of paragraph 13 of the First Amended Complaint, except admits that Synthes (U.S.A.) manufactures, markets and sells the accused TFN intramedullary nail product in the United States.

14. Synthes (U.S.A.) denies the allegations set forth in paragraph 14 of the First Amended Complaint.

15. Synthes (U.S.A.) denies the allegations set forth in paragraph 15 of the First Amended Complaint.

COUNT TWO: INFRINGEMENT OF U.S. PATENT NO. 5,167,663

16. Synthes (U.S.A.) realleges and incorporates by reference its responses to paragraphs 1-15 inclusive as if fully set forth herein in response to the allegations of paragraph 16 of the First Amended Complaint.

17. Synthes (U.S.A.) has insufficient knowledge and information to form a belief as to the truthfulness of the allegations set forth in paragraph 17 of the First Amended Complaint, and therefore denies the allegations set forth therein, except that it admits that U.S. Patent No. 5,167,663 ("the '663 patent") was issued on December 1, 1994.

18. Synthes (U.S.A.) denies the allegations set forth in the second paragraph numbered "paragraph 17" of the First Amended Complaint.

19. Synthes (U.S.A.) denies the allegations of paragraph 18 of the First Amended Complaint, except that it admits that Synthes (U.S.A.) manufactures, markets and sells the accused TFN intramedullary nail product in the United States.

20. Synthes (U.S.A.) denies the allegations of paragraph 19 of the First Amended Complaint.

21. Synthes (U.S.A.) denies the allegations of paragraph 20 of the First Amended Complaint.

AFFIRMATIVE DEFENSES

Synthes (U.S.A.) asserts the following affirmative defenses against the claims made by plaintiff in its Complaint.

FIRST AFFIRMATIVE DEFENSE

22. The Court lacks personal jurisdiction over Synthes-Stratec Inc., Synthes North America, Inc. and Synthes, Inc.

SECOND AFFIRMATIVE DEFENSE

23. The First Amended Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

24. The '663 and '406 patents are invalid and void for their failure to meet the conditions for patentability set forth in Title 35, United States Code, §§ 101 *et seq.* and more particularly fail to comply with the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 thereof.

FOURTH AFFIRMATIVE DEFENSE

25. No product manufactured, used, offered for sale, sold or imported by Synthes (U.S.A.) infringes any valid claim of the '406 or '663 patents, and Synthes (U.S.A.) is not actively inducing or contributing to the infringement thereof by third parties.

FIFTH AFFIRMATIVE DEFENSE

26. By reason of proceedings in the United States Patent and Trademark Office during prosecution of the applications leading to the issuance of the '406 and '663 patents, including their parent applications, plaintiff is estopped from asserting that Synthes (U.S.A.) has infringed or is infringing the '406 or '663 patents and are estopped from maintaining an action against Synthes (U.S.A.)

SIXTH AFFIRMATIVE DEFENSE

27. The '406 patent is unenforceable for inequitable conduct during prosecution of the application leading to issuance of the '406 patent in that applicant and his attorneys, upon

information and belief, deliberately and knowingly misrepresented material information, including, but not limited to, the following: on September 16, 1993 the applicant, through his attorneys, submitted a Supplemental Response to the Office Action of January 22, 1993, in which he inaccurately and misleadingly stated "Claim 23 includes amendment to previous Claim 4 as amended by Applicant on May 24, 1993. It is believed that the new Claim 23 is allowable for the same reasons that are outlined in the Remarks section of the May 24, 1993 Response." Applicant and/or his attorneys made this statement in order to induce the Examiner to allow claims 23 when in fact claim 23 did not include the amendments that were made to claim 4 on May 24, 1993. As a result of these false statements, the Examiner allowed pending claim 23, which ultimately issued as claim 1 of the '406 patent.

WHEREFORE, SYNTHES (U.S.A.) prays for a final judgment that:

1. This Court lacks personal jurisdiction over Synthes-Stratec, Inc., Synthes North America, Inc., and Synthes Inc.;
2. The '406 patent is invalid, void and unenforceable;
3. The '406 patent is not infringed by Synthes (U.S.A.)'s manufacture, use, offer for sale, sale or importation of its TFN intramedullary nail product;
4. The '663 patent is invalid, void and unenforceable;
5. The '663 patent is not infringed by Synthes (U.S.A.)'s manufacture, use, offer for sale, sale or importation of its TFN intramedullary nail product;
6. Plaintiff, its officers, agents, employees, attorneys and/or persons in active concert or participation with them be permanently enjoined from suing or threatening to sue or making any charge against Synthes (U.S.A.) or its suppliers, distributors or

customers concerning alleged infringement of the '406 or '663 patents by Synthes (U.S.A.)'s TFN intramedullary nail product;

7. This action be judged an exceptional case and Synthes (U.S.A.) be awarded its costs and reasonable attorney fees incurred in this Action; and

8. Synthes (U.S.A.) be awarded such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: April 14, 2003

By: _____
James E. Conley, Jr.

THOMASON, HENDRIX, HARVEY,
JOHNSON & MITCHELL
One Commerce Square, 40 South Main
Memphis, Tennessee 38103
(901) 525-8721

Attorneys for Defendants,
Synthes (U.S.A.), Synthes-Stratec, Inc.,
Synthes, Inc. and Synthes North America, Inc.

OF COUNSEL:

Brian M. Poissant
Brian M. Rothery
Andrew J. Wu
Howard I. Shin
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, NY 10036
(212) 790-9090

CERTIFICATE OF SERVICE

This is to certify that a copy of SYNTHES (U.S.A.)'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT, has been provided by hand to:

Mark Vorder-Bruegge, Jr.
WYATT, TARRANT & COMBS LLP
1715 Aaron Brenner Drive, Suite 800
Memphis, TN 38120

and has been provided by Federal Express to:

James R. Myers
Kenneth A. Godlewski
KILPATRICK STOCKTON LLP
Suite 900, 607 Fourteenth Street, NW
Washington, DC 20005

on this 14 day of April, 2003.

James E. Conley, Jr.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE

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W.D. OF [illegible] MEMPHIS

SMITH & NEPHEW, INC.,

Plaintiff,

v.

SYNTHES (U.S.A.) and SYNTHES-STRATEC, INC.

Defendants.

Civil Action No. 02-CV-2873

Judge Samuel H. Mays, Jr.

SYNTHES-STRATEC, INC.'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT

Defendant Synthes-Stratec, Inc. ("Synthes-Stratec"), for its answer to plaintiff's First Amended Complaint states as follows[1]:

PARTIES

1. Synthes-Stratec has insufficient knowledge or information to form a belief as to the allegations of paragraph 1 of the First Amended Complaint, and, accordingly, denies the same.

2. Synthes-Stratec has insufficient knowledge or information to form a belief as to plaintiff's intent to sue Synthes (U.S.A.) on or about November 13, 2002; and otherwise denies the remaining allegations of paragraph 2 of the First Amended Complaint, except upon information and belief admits that Synthes (U.S.A.) is a Pennsylvania partnership in the business of developing, manufacturing, and selling orthopedic implants and intramedullary nails in the United States on a nationwide basis; that Synthes (U.S.A.)'s principal place of business and

[1] Synthes-Stratec does not waive its objections to personal jurisdiction and venue in this forum initially raised in its Motion to Dismiss and Motion to Transfer, both filed on February 20, 2003.

headquarters is at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes (U.S.A.) has two general partners, Synthes, Inc. and Synthes North America, Inc. Synthes-Stratec admits that it owns 100% of the shares of Synthes North America, Inc. and 100% of the shares of Synthes, Inc.

3. Synthes-Stratec denies the allegations set forth in paragraph 3 of the First Amended Complaint, except that it admits that it is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that it owns 100% of the stock of Synthes, Inc. and Synthes North America, Inc.

4. Synthes-Stratec denies the allegations set forth in paragraph 4 of the First Amended Complaint, except that it admits that Synthes, Inc. is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes, Inc. is a 60% general partner of Synthes (U.S.A.).

5. Synthes-Stratec denies the allegations set forth in paragraph 5 of the First Amended Complaint, except that it admits that Synthes North America, Inc. is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes North America, Inc. is a 40% general partner of Synthes (U.S.A.).

JURISDICTION AND VENUE

6. Synthes-Stratec admits the allegations set forth in paragraph 6 of the First Amended Complaint.

7. Synthes-Stratec denies the allegations set forth in paragraph 7 of the First Amended Complaint, except that it admits that Synthes (U.S.A.) is subject to personal jurisdiction in Tennessee.

8. Synthes-Stratec denies the allegations set forth in paragraph 8 of the First Amended Complaint.

9. Synthes-Stratec denies the allegations set forth in paragraph 9 of the First Amended Complaint, except that Synthes-Stratec admits that venue in this district is proper as to Synthes (U.S.A.).

COUNT ONE: INFRINGEMENT OF U.S. PATENT NO. 5,312,406

10. Synthes-Stratec realleges and incorporates by reference paragraphs 1-9 inclusive above as if fully set forth herein in response to the allegations of paragraph 10 of the First Amended Complaint.

11. Synthes-Stratec has insufficient knowledge and information to form a belief as to the allegations set forth in paragraph 11 of the First Amended Complaint, and, therefore, denies the allegations set forth therein, except Synthes-Stratec admits that U.S. Patent No. 5,312,406 ("the '406 patent") was issued on May 17, 1994.

12. Synthes-Stratec denies the allegations of paragraph 12 of the First Amended Complaint.

13. Synthes-Stratec denies the allegations of paragraph 13 of the First Amended Complaint, except Synthes-Stratec upon information and belief admits that Synthes (U.S.A.) manufactures, markets and sells the accused TFN intramedullary nail product in the United States.

14. Synthes-Stratec denies the allegations set forth in paragraph 14 of the First Amended Complaint.

15. Synthes-Stratec denies the allegations set forth in paragraph 15 of the First Amended Complaint.

COUNT TWO: INFRINGEMENT OF U.S. PATENT NO. 5,167,663

16. Synthes-Stratec realleges and incorporates by reference its responses to paragraphs 1-15 inclusive as if fully set forth herein in response to the allegations of paragraph 16 of the First Amended Complaint.

17. Synthes-Stratec has insufficient knowledge and information to form a belief as to the truthfulness of the allegations set forth in paragraph 17 of the First Amended Complaint, and therefore denies the allegations set forth therein, except that it admits that U.S. Patent No. 5,167,663 ("the '663 patent") was issued on December 1, 1994.

18. Synthes-Stratec denies the allegations set forth in the second paragraph numbered "17" of the First Amended Complaint.

19. Synthes-Stratec denies the allegations of paragraph 18 of the First Amended Complaint, except that it admits that Synthes (U.S.A.) manufactures, markets and sells the accused TFN intramedullary nail product in the United States.

20. Synthes-Stratec denies the allegations of paragraph 19 of the First Amended Complaint.

21. Synthes-Stratec denies the allegations of paragraph 20 of the First Amended Complaint.

AFFIRMATIVE DEFENSES

Synthes-Stratec asserts the following affirmative defenses against the claims made by plaintiff in its Complaint.

FIRST AFFIRMATIVE DEFENSE

22. The Court lacks personal jurisdiction over Synthes-Stratec, Inc.

SECOND AFFIRMATIVE DEFENSE

23. The First Amended Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

24. The '663 and '406 patents are invalid and void for their failure to meet the conditions for patentability set forth in Title 35 United States Code, §§ 101 *et seq.*, and more particularly fail to comply with the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 thereof.

FOURTH AFFIRMATIVE DEFENSE

25. No product manufactured, used, offered for sale, sold or imported by Synthes-Stratec infringes any valid claim of the '406 or '663 patents, and Synthes-Stratec does not induce infringement or contribute to the infringement thereof by any other party.

FIFTH AFFIRMATIVE DEFENSE

26. Synthes-Stratec is not liable for any alleged act of infringement committed by Synthes (U.S.A.).

SIXTH AFFIRMATIVE DEFENSE

27. By reason of proceedings in the United States Patent and Trademark Office during prosecution of the applications leading to the issuance of the '406 and '663 patents, including their parent applications, plaintiff is estopped from asserting that Synthes-Stratec has

infringed or is infringing the '406 or '663 patents and are estopped from maintaining an action against Synthes-Stratec

SEVENTH AFFIRMATIVE DEFENSE

28. The '406 patent is unenforceable for inequitable conduct during prosecution of the application leading to issuance of the '406 patent in that applicant and his attorneys, upon information and belief, deliberately and knowingly misrepresented material information, including, but not limited to, the following: on September 16, 1993 the applicant, through his attorneys, submitted a Supplemental Response to the Office Action of January 22, 1993, in which he inaccurately and misleadingly stated "Claim 23 includes amendment to previous Claim 4 as amended by Applicant on May 24, 1993. It is believed that the new Claim 23 is allowable for the same reasons that are outlined in the Remarks section of the May 24, 1993 Response." Applicant and/or his attorneys made this statement in order to induce the Examiner to allow claims 23 when in fact claim 23 did not include the amendments that were made to claim 4 on May 24, 1993. As a result of these false statements, the Examiner allowed pending claim 23, which ultimately issued as claim 1 of the '406 patent.

WHEREFORE, SYNTHES-STRATEC prays for a final judgment that:

1. This Court lacks personal jurisdiction over Synthes-Stratec, Inc.;
2. Synthes-Stratec, Inc. is not an alter-ego of Synthes (U.S.A.);
3. Synthes-Stratec is not liable for the acts of Synthes (U.S.A.);
4. Synthes-Stratec does not make, use, sell or offer to sell, or import the accused TFN intramedullary nail product.
5. The '406 patent is invalid, void and unenforceable;

6. The '406 patent is not infringed by Synthes (U.S.A.)'s manufacture, use, offer for sale, sale or importation of its TFN intramedullary nail product;

7. The '406 patent is not infringed by Synthes-Stratec;

8. The '663 patent is invalid, void and unenforceable;

9. The '663 patent is not infringed by Synthes (U.S.A.)'s manufacture, use, offer for sale, sale or importation of its TFN intramedullary nail product;

10. The '663 patent is not infringed by Synthes-Stratec;

11. Plaintiff, its officers, agents, employees, attorneys and/or persons in active concert or participation with them be permanently enjoined from suing or threatening to sue or making any charge against Synthes-Stratec concerning alleged infringement of the '406 or '663 patents by the TFN intramedullary nail product;

12. This action be judged an exceptional case and Synthes-Stratec be awarded its costs and reasonable attorney fees incurred in this Action; and

13. Synthes-Stratec be awarded such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: October 16, 2003

By: _____
James E. Conley, Jr.

THOMASON, HENDRIX, HARVEY,
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One Commerce Square, 40 South Main
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Attorneys for Defendants,
Synthes (U.S.A.) and Synthes-Stratec, Inc.

OF COUNSEL:

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New York, NY 10036
(212) 790-9090

CERTIFICATE OF SERVICE

This is to certify that a copy of SYNTHES-STRATEC'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT, has been provided by hand to:

Mark Vorder-Bruegge, Jr.
WYATT, TARRANT & COMBS LLP
1715 Aaron Brenner Drive, Suite 800
Memphis, TN 38120

and has been provided by Federal Express to:

Kenneth A. Godlewski
KILPATRICK STOCKTON LLP
Suite 900, 607 Fourteenth Street, NW
Washington, DC 20005

on this 16 day of October, 2003.

James E. Conley, Jr.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE

SMITH & NEPHEW, INC., Plaintiff, v. SYNTHES (U.S.A.) and SYNTHES-STRATEC, INC., Defendants.	Case No. 02-CV-2873 Judge Samuel H. Mays, Jr.

AMENDMENT TO THE FIRST AMENDED COMPLAINT

Pursuant to leave granted by the Court, Plaintiff Smith & Nephew hereby makes the following amendments to the First Amended Complaint:

a) Deletion of Synthes Inc. and Synthes North America, Inc. who have been dismissed without prejudice.

b) Amendments to pages 6, 7, and 8 as follows to assert monetary damages:

"15. Smith & Nephew has been and will continue to be damaged by the infringement of Defendants, ~~resulting in irreparable injury unless such infringement is enjoined by this Court.~~ Therefore, Smith & Nephew is entitled to injunctive relief and to recover from Defendants its damages, including increased damages for willful infringement, interests, costs, and reasonable attorneys' fees, pursuant to 35 U.S.C. §§ 284-285."

***

"20. Smith & Nephew has been and will continue to be damaged by the infringement of Defendants, ~~resulting in irreparable injury unless such infringement is enjoined by this Court.~~ Therefore, Smith & Nephew is entitled to injunctive relief and to recover from Defendants its damages, including increased damages for willful infringement, interests, costs, and reasonable attorneys' fees, pursuant to 35 U.S.C. §§ 284-285."

***

"E. Awarding damages together with interests and costs pursuant to 35 U.S.C. 284 adequate to compensate Smith & Nephew for said infringement, but in no event less than a reasonable royalty;

F. Ordering an accounting to determine the proper amount of such damages;

G. Increasing such damages three-fold as a result of willful, wanton and deliberate acts of infringement;

~~E.~~H. Adjudging this to be an exceptional case pursuant to 35 U.S.C. § 285, and awarding Smith & Nephew its attorneys' fees in this action; and

~~F.~~I. Granting such further relief as the Court deems just and proper."

Respectfully submitted,

Mark Vorder-Bruegge by [illegible]

Mark Vorder-Bruegge, Jr. (6389)
WYATT, TARRANT & COMBS, LLP
P.O. Box 775000
Memphis, TN 38177-5000
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Memphis, TN 38120-4367

ATTORNEYS FOR PLAINTIFF
SMITH & NEPHEW, INC.

Of Counsel

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Kenneth A. Godlewski (admitted *Pro Hac Vice)*
Stephen E. Baskin (admitted *Pro Hac Vice)*
KILPATRICK STOCKTON LLP
Suite 900
607 Fourteenth Street, NW
Washington, DC 20005
Phone: 202-508-5800
Fax: 202-508-5858

CERTIFICATE OF SERVICE

The undersigned attorney for Plaintiff Smith & Nephew, Inc. hereby certifies that a copy of the foregoing paper was duly served on all defendants in this action, on January 23, 2004, by delivery to the following by the method indicated:

Mr. James E. Conley, Jr.
Thomason, Hendrix, Harvey,
Johnson & Mitchell, PLLC
29th Floor, One Commerce Square
40 South Main Street
Memphis, Tennessee 38103-5529
(Hand Delivery)

Mr. Brian M. Poissant
Jones Day
222 East 41st Street
New York, NY 10017-6702
(Federal Express)

~~Mark Yorder-Bruegge, Jr.~~
Kim Konatzky

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE

SMITH & NEPHEW, INC., Plaintiff, v. SYNTHES (U.S.A.) and SYNTHES-STRATEC, INC. Defendants.	Civil Action No. 02-CV-2873 Judge Samuel H. Mays, Jr.

AMENDED ANSWER AND COUNTERCLAIMS

Defendants Synthes (U.S.A.) and Synthes-Stratec, Inc. (collectively "Defendants") for their answer to Plaintiff's Amendment to the First Amended Complaint, served on January 23, 2004, state as follows:

PARTIES

1. Defendants have insufficient knowledge or information to form a belief as to the allegations of paragraph 1 of the First Amended Complaint, and, accordingly, deny the same.

2. Defendants have insufficient knowledge or information to form a belief as to Plaintiff's intent to sue Synthes (U.S.A.) on or about November 13, 2002; and otherwise deny the remaining allegations of paragraph 2 of the First Amended Complaint, except Defendants admit that Synthes (U.S.A.) is a Pennsylvania partnership in the business of developing, manufacturing, and selling orthopedic implants and intramedullary nails in the United States on a nationwide basis, that Synthes (U.S.A.)'s principal place of business and headquarters is at 1690 Russell Road, Paoli, Pennsylvania 19301, and that it has two general partners, Synthes, Inc. and Synthes North America, Inc., and that Synthes-Stratec, Inc. owns 100% of the shares of Synthes North America, Inc. and 100% of the shares of Synthes, Inc.

3. Defendants deny the allegations set forth in paragraph 3 of the First Amended Complaint, except that Defendants admit that Synthes-Stratec, Inc. is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes-Stratec, Inc. owns 100% of the stock of Synthes, Inc. and Synthes North America, Inc.

4. Defendants deny the allegations set forth in paragraph 4 of the First Amended Complaint, except that Defendants admit that Synthes, Inc. is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes, Inc. is a 60% general partner of Synthes (U.S.A.).

5. Defendants deny the allegations set forth in paragraph 5 of the First Amended Complaint, except that Defendants admit that Synthes North America, Inc. is a Delaware corporation having its principal place of business and corporate headquarters at 1690 Russell Road, Paoli, Pennsylvania 19301, and that Synthes North America, Inc. is a 40% general partner of Synthes (U.S.A.).

JURISDICTION AND VENUE

6. Defendants admit the allegations set forth in paragraph 6 of the First Amended Complaint.

7. Defendants deny the allegations set forth in paragraph 7 of the First Amended Complaint, except that they admit that Synthes (U.S.A.) is subject to personal jurisdiction in Tennessee.

8. Defendants deny the allegations set forth in paragraph 8 of the First Amended Complaint.

9. Defendants deny the allegations set forth in paragraph 9 of the First Amended Complaint, except that they admit that venue in this district is proper as to Synthes (U.S.A.).

COUNT ONE: INFRINGEMENT OF U.S. PATENT NO. 5,312,406

10. Defendants reallege and incorporate by reference paragraphs 1-9 inclusive above as if fully set forth herein in response to the allegations set forth in paragraph 10 of the First Amended Complaint.

11. Defendants have insufficient knowledge and information to form a belief as to the allegations set forth in paragraph 11 of the First Amended Complaint, and, therefore, deny the allegations set forth therein, except that Defendants admit that U.S. Patent No. 5,312,406 ("the '406 patent") was issued on May 17, 1994.

12. Defendants deny the allegations set forth in paragraph 12 of the First Amended Complaint.

13. Defendants deny the allegations set forth in paragraph 13 of the First Amended Complaint, except that Defendants admit that Synthes (U.S.A.) manufactures, markets and sells the accused TFN intramedullary nail product in the United States.

14. Defendants deny the allegations set forth in paragraph 14 of the First Amended Complaint.

15. Defendants deny the allegations set forth in paragraph 15 as amended by Plaintiff's January 23, 2004 Amendment to the First Amended Complaint.

COUNT TWO: INFRINGEMENT OF U.S. PATENT NO. 5,167,663

16. Defendants reallege and incorporate by reference paragraphs 1-15 inclusive above as if fully set forth herein in response to the allegations set forth in paragraph 16 of the First Amended Complaint.

17. Defendants have insufficient knowledge and information to form a belief as to the allegations set forth in paragraph 17 of the First Amended Complaint, and, therefore, deny the allegations set forth therein, except that Defendants admit that U.S. Patent No. 5,167,663 ("the '663 patent") was issued on December 1, 1994.

18. Defendants deny the allegations set forth in the second paragraph numbered "17" of the First Amended Complaint.

19. Defendants deny the allegations set forth in paragraph 18 of the First Amended Complaint, except that they admit that Synthes (U.S.A.) manufactures, markets and sells the accused TFN intramedullary nail product in the United States.

20. Defendants deny the allegations set forth in paragraph 19 of the First Amended Complaint.

21. Defendants deny the allegations of paragraph 20 as amended by Plaintiff's January 23, 2004 Amendment to the First Amended Complaint.

ADDITIONAL AND AFFIRMATIVE DEFENSES

Defendants asserts the following additional and affirmative defenses against the claims made by Plaintiff in its First Amended Complaint.

22. The Court lacks personal jurisdiction over Synthes-Stratec, Inc.

23. The First Amended Complaint fails to state a claim upon which relief can be granted.

24. The '406 and '663 patents are invalid and void for their failure to meet the conditions for patentability set forth in Title 35, United States Code, §§ 101 *et seq.* and, more particularly, fail to comply with the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 thereof.

25. No product manufactured, used, offered for sale, sold or imported by Defendants infringes any valid claim of the '406 or '663 patents, and Defendants are not actively inducing or contributing to the infringement thereof by third parties.

26. Defendant Synthes-Stratec, Inc. is not liable for any alleged act of infringement committed by Defendant Synthes (U.S.A.).

27. By reason of proceedings in the United States Patent and Trademark Office during prosecution of the applications leading to the issuance of the '406 and '663 patents, including their parent applications and subsequent related applications, Plaintiff is estopped from asserting that Defendants have infringed or are infringing the '406 or '663 patents and is estopped from maintaining this infringement action against Defendants.

28. The '406 patent is unenforceable for inequitable conduct during prosecution of the application leading to issuance of the '406 patent in that applicant and/or his attorneys, upon information and belief, deliberately and knowingly misrepresented material information, including, but not limited to, the following: on or about September 16, 1993 the applicant, through his attorneys, submitted a Supplemental Response to the Office Action of January 22, 1993, in which he inaccurately and misleadingly stated "Claim 23 includes amendment to previous Claim 4 as amended by Applicant on May 24, 1993. It is believed that the new Claim 23 is allowable for the same reasons that are outlined in the Remarks section of the May 24, 1993 Response." Applicant and/or his attorneys made this statement in order to induce the Examiner to allow claims 23 when in fact claim 23 did not include the amendments that were made to claim 4 on May 24, 1993. As a result of these false statements, the Examiner allowed pending claim 23, which ultimately issued as claim 1 of the '406 patent.

29. Upon information and belief, Plaintiff Smith & Nephew is barred from recovering damages for the period of time prior to the filing of this action due to the failure of Plaintiff and/or the alleged prior assignees of the '406 and '663 patents to comply with the marking requirements of 35 U.S.C. § 287(a).

30. Pursuant to 35 U.S.C. § 286, Plaintiff is barred from recovering damages for any alleged act of infringement which occurred more than six years prior to the filing of this action.

31. Plaintiff's claims are barred by laches.

32. Defendants reserve the right to assert additional defenses or affirmative defenses as revealed through discovery.

COUNTERCLAIMS

Counterclaim Plaintiff Synthes (U.S.A.), for its Counterclaims against Counterclaim Defendant, Smith & Nephew, Inc. ("Smith & Nephew"), alleges:

PARTIES

33. Counterclaim Plaintiff Synthes (U.S.A.) is a Pennsylvania partnership with a principal place of business located at 1690 Russell Road, Paoli, Pennsylvania 19301. Synthes (U.S.A.) is in the business of developing, manufacturing and selling various orthopedic products, including a trochanteric intramedullary fixation nail ("TFN intramedullary nail"), related systems, and other similar devices.

34. Upon information and belief, Counterclaim Defendant Smith & Nephew is a Delaware corporation having a principal place of business in Memphis, Tennessee.

JURISDICTION AND VENUE

35. Upon information and belief, Counterclaim Defendant Smith & Nephew has its principal place of business in and conducts business in Tennessee and in this judicial district by

offering to sell and by selling orthopedic implants, instruments and other devices to customers located in Tennessee and in this judicial district.

36. This is a civil action arising under the patent laws of the United States, Title 35, United States Code, and under the Federal Declaratory Judgment Act, Title 28, United States Code. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. This Court has personal jurisdiction over Counterclaim Defendant Smith & Nephew, and venue in this judicial district is proper under 28 U.S.C. §§ 1391 and 1400(b).

37. The Counterclaims asserted herein were originally asserted by Synthes (U.S.A.) in an action entitled Synthes (U.S.A.) v. Smith & Nephew, Inc., Civil Action No. 03-CV-0083 (E.D. Pa.). On or about September 16, 2003, that action was ordered transferred to the United States District Court for the Western District of Tennessee, and, on or about November 4, 2003, it was consolidated with the present action, Smith & Nephew, Inc. v. Synthes (U.S.A.) et al., Civil Action No. 02-CV-2873.

FIRST COUNTERCLAIM
(U.S. PATENT NO. 5,312,406 IS INVALID, UNENFORCEABLE AND NOT INFRINGED)

38. Counterclaim Plaintiff Synthes (U.S.A.) incorporates and realleges the allegations in Paragraphs 33-37 as if fully set forth herein.

39. Upon information and belief, Counterclaim Defendant Smith & Nephew owns an undivided interest in United States Patent No. 5,312,406, entitled "Method of Treating an Intertrochanteric Fracture," which issued on May 17, 1994 ("'406 patent"), by way of an assignment from David L. Brumfield. Upon information and belief, Smith & Nephew or its predecessor-in-interest, Smith & Nephew Richards, Inc., has owned an undivided interest since the issuance of the '406 patent.

40. The '406 patent is invalid, void and unenforceable against Counterclaim Plaintiff Synthes (U.S.A.) for failure to comply with the requirements of 35 U.S.C. § 101, *et seq.*, including 35 U.S.C. §§ 101, 102, 103 and/or 112.

41. The manufacture, use, offer for sale, sale or importation by Counterclaim Plaintiff Synthes (U.S.A.) of its TFN intramedullary nail, related systems and other similar devices does not infringe any valid claim of the '406 patent.

42. On or about November 13, 2002, Counterclaim Defendant Smith & Nephew filed suit in this judicial district against Defendant Synthes-Stratec, Inc., among others, alleging that the TFN intramedullary nail infringes the '406 patent. On or about January 21, 2003, Counterclaim Defendant Smith & Nephew amended its complaint to add Counterclaim Plaintiff Synthes (U.S.A.) as a party and alleged that Synthes (U.S.A.)'s making, using, offering to sell and selling of the TFN intramedullary nail infringes the '406 patent.

43. By reason of the foregoing, a conflict of asserted rights has arisen and a justiciable controversy exists between Counterclaim Plaintiff Synthes (U.S.A.) and Counterclaim Defendant Smith & Nephew with regard to the validity, enforceability and infringement of the '406 patent, and as to the rights of Synthes (U.S.A.) to continue to manufacture, use, offer for sale, sell, or import its TFN intramedullary nail, related systems and other similar devices in the United States free from further interference by Smith & Nephew.

44. By reason of the foregoing, Counterclaim Plaintiff Synthes (U.S.A.) has been irreparably harmed and will continue to be so harmed thereby.

45. By reason of the foregoing and the totality of Counterclaim Defendant Smith & Nephew's conduct, this is an exceptional case within the meaning of 35 U.S.C. § 285 and this

Court may properly award Counterclaim Plaintiff Synthes (U.S.A.) its reasonable attorneys fees and costs incurred in this action.

SECOND COUNTERCLAIM
(U.S. PATENT NO. 5,167,663 IS INVALID, UNENFORCEABLE AND NOT INFRINGED)

46. Counterclaim Plaintiff Synthes (U.S.A.) incorporates and realleges the allegations of paragraphs 33-45 as if fully forth herein.

47. Upon information and belief, Counterclaim Defendant Smith & Nephew owns an undivided interest in United States patent No. 5,167,663, entitled "Femoral Fracture Device," which issued on December 1, 1992 ("'663 patent"), by way of an assignment from David L. Brumfield. Upon information and belief, Smith & Nephew or its predecessor-in-interest, Smith & Nephew Richards, Inc., has owned an undivided interest since the issuance of the '663 patent.

48. The '663 patent is invalid, void and unenforceable against Counterclaim Plaintiff Synthes (U.S.A.) for failure to comply with the requirements of 35 U.S.C. § 101, *et seq.*, including 35 U.S.C. §§ 101, 102, 103 and/or 112.

49. The manufacture, use, offer for sale, sale or importation by Counterclaim Plaintiff Synthes (U.S.A.) of its TFN intramedullary nail, related systems and other similar devices does not infringe any valid claim of the '663 patent.

50. On or about November 13, 2002, Counterclaim Defendant Smith & Nephew filed suit in this judicial district against Synthes-Stratec, Inc., among others, alleging that the TFN intramedullary nail infringes the '663 patent. On or about January 21, 2003, Counterclaim Defendant Smith & Nephew amended its complaint to add Counterclaim Plaintiff Synthes (U.S.A.) as a party and alleged that Synthes (U.S.A.)'s making, using, offering to sell and selling of the TFN intramedullary nail infringes the '663 patent.

51. By reason of the foregoing, a conflict of asserted rights has arisen and a justiciable controversy exists between Counterclaim Plaintiff Synthes (U.S.A.) and Counterclaim Defendant Smith & Nephew with regard to the validity, enforceability and infringement of the '663 patent, and as to the rights of Synthes (U.S.A.) to continue to manufacture, use, offer for sale, sell, or import its TFN intramedullary nail, related systems, and other similar devices in the United States free from further interference by Smith & Nephew.

52. By reason of the foregoing, Counterclaim Plaintiff Synthes (U.S.A.) has been irreparably harmed and will continue to be so harmed thereby.

53. By reason of the foregoing and the totality of the Counterclaim Defendant Smith & Nephew's conduct, this is an exceptional case within the meaning of 35 U.S.C. § 285 and this Court may properly award Counterclaim Plaintiff Synthes (U.S.A.) its reasonable attorneys fees and costs incurred in the prosecution of this action.

WHEREFORE, SYNTHES (U.S.A.) AND SYNTHES-STRATEC, INC. pray for a final judgment that:

A. This Court lacks personal jurisdiction over Defendant Synthes-Stratec, Inc.;

B. Defendant Synthes-Stratec, Inc. is not liable for any alleged act of infringement by Defendant Synthes (U.S.A.).

C. The '406 patent is invalid, void and unenforceable;

D. The '406 patent is not infringed by the manufacture, use, offer for sale, sale or importation of Defendant/Counterclaim Plaintiff Synthes (U.S.A.)'s TFN intramedullary nail, related systems or other similar devices;

E. Plaintiff/Counterclaim Defendant Smith & Nephew, its officers, agents, employees, attorneys and/or persons in active concert or participation with them

be permanently enjoined from suing or threatening to sue or making any charge of infringement against Defendants, or their suppliers, distributors or customers, concerning alleged infringement of the '406 patent by Defendant/Counterclaim Plaintiff Synthes (U.S.A.)'s TFN intramedullary nail product, related systems or other similar devices;

F. The '663 patent is invalid, void and unenforceable;

G. The '663 patent is not infringed by the manufacture, use, offer for sale, sale or importation of Defendant/Counterclaim Plaintiff Synthes (U.S.A.)'s TFN intramedullary nail product, related systems or other similar devices;

H. Plaintiff/Counterclaim Defendant Smith & Nephew, its officers, agents, employees, attorneys and/or persons in active concert or participation with them be permanently enjoined from suing or threatening to sue or making any charge of infringement against Defendants or their suppliers, distributors or customers concerning alleged infringement of the '663 patent by Defendant/Counterclaim Plaintiff Synthes (U.S.A.)'s TFN intramedullary nail product, related systems or other similar devices;

I. This action be judged an exceptional case pursuant to at least 35 U.S.C. § 285, and Defendants be awarded their costs and reasonable attorney fees incurred in this action; and

J. Defendants be awarded such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: February 27, 2004

By: _____
James E. Conley, Jr.

THOMASON, HENDRIX, HARVEY, JOHNSON & MITCHELL
One Commerce Square, 40 South Main
Memphis, Tennessee 38103
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Attorneys for Defendants,
Synthes (U.S.A.) and Synthes-Stratec, Inc.

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing AMENDED ANSWER AND COUNTERCLAIMS was served upon counsel for Plaintiff by the method indicated:

By Hand
Mark Vorder-Bruegge, Jr.
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Atlanta, GA 30309

on this 27th day of February, 2004.

James E. Conley, Jr.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE

SMITH & NEPHEW, INC.,

Plaintiff,

v. Case No. 02-CV-2873

SYNTHES (U.S.A.) and SYNTHES-STRATEC, INC., Judge Samuel H. Mays, Jr.

Defendants.

SMITH & NEPHEW'S REPLY TO SYNTHES (U.S.A)'S COUNTERCLAIMS

Plaintiff Smith & Nephew, Inc. ("Smith & Nephew") hereby replies to the counterclaims of Defendant Synthes (U.S.A.) as follows:

1. Admits as to paragraph 33, on information and belief, that Synthes (U.S.A.) is a Pennsylvania partnership with a principal place of business located at 1690 Russell Road, Paoli, Pennsylvania; and that Synthes (U.S.A.) is in the business of developing, manufacturing and selling various orthopedic products, including the Trochanteric Fixation Nail ("TFN"), related systems, and other similar devices.

2. Admits as to paragraph 34 that Smith & Nephew, Inc. is a Delaware corporation having a principal place of business in Memphis, Tennessee.

3. Admits as to paragraph 35 that Smith & Nephew has its principal place of business in and conducts business in Tennessee and in this judicial district by offering to sell and by selling orthopedic implants, instruments and other devices to customers located in Tennessee and in this judicial district.

4. Admits as to paragraph 36 that this is a civil action arising under the patent laws of the United States, Title 35, United States Code, and under the Federal Declaratory Judgment Act, Title 28, United States Code. Admits this Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202; and this Court has personal jurisdiction over Smith & Nephew, and venue in this judicial district is proper under 28 U.S.C. §§ 1391 and 1400(b).

5. Admits as to paragraph 37 that the Counterclaims asserted herein were originally asserted by Synthes (U.S.A.) in an action entitled Synthes (U.S.A.) v. Smith & Nephew, Inc., Civil Action No. 03-CV-0083 (E.D. Pa.). Admits that on or about September 16, 2003, that action was ordered transferred to the United States District Court for the Western District of Tennessee, and on or about November 4, 2003, it was consolidated with the present action, Smith & Nephew, Inc. v. Synthes (U.S.A.) et al., Civil Action No. 02-CV-2873.

6. As to paragraph 38, Smith & Nephew incorporates by reference its replies to paragraphs 33 through 37 above, as though fully stated herein.

7. Admits as to paragraph 39 that Smith & Nephew owns an undivided interest in United States Patent No. 5,312,406, entitled "Method of Treating an Intertrochanteric Fracture," which issued on May 17, 1994 ("the '406 patent"), by way of an assignment from David L. Brumfield. Smith & Nephew or its predecessor-in-interest, Smith & Nephew Richards, Inc., has owned an undivided interest since the issuance of the '406 patent.

8. Denies the allegations set forth in paragraph 40.

9. Denies the allegations set forth in paragraph 41.

10. Admits as to paragraph 42 that on or about November 13, 2002, Smith & Nephew filed suit in this judicial district against Synthes-Stratec, Inc. and Synthes USA, Inc., alleging that the TFN intramedullary nail infringes the '406 patent. On or about January 21, 2003, Smith & Nephew amended its complaint to add Synthes (U.S.A.) as a party and alleged that Synthes (U.S.A.)'s making, using, offering to sell and selling of the TFN intramedullary nail infringes the '406 patent.

11. Admits as to paragraph 43 that a justiciable controversy exists between Synthes (U.S.A.) and Smith & Nephew as to the rights of Synthes (U.S.A.) to continue to manufacture, use, offer for sale, sell, or import its TFN intramedullary nail, related systems and other similar devices in the United States in view of its infringement of Smith & Nephew's valid and enforceable '406 patent.

12. Denies the allegations set forth in paragraph 44.

13. Denies the allegations set forth in paragraph 45.

14. As to paragraph 46, Smith & Nephew incorporates by reference its replies to paragraphs 33 through 45 above, as though fully stated herein.

15. Admits as to paragraph 47 that Smith & Nephew owns an undivided interest in United States Patent No. 5,167,663, entitled "Femoral Fracture Device," which issued on December 1, 1992 ("the '663 patent"), by way of an assignment from David L. Brumfield. Smith & Nephew or its predecessor-in-interest, Smith & Nephew Richards, Inc., has owned an undivided interest since the issuance of the '663 patent.

16. Denies the allegations set forth in paragraph 48.

17. Denies the allegations set forth in paragraph 49.

18. Admits as to paragraph 50 that on or about November 13, 2002, Smith & Nephew filed suit in this judicial district against Synthes-Stratec, Inc. and Synthes USA, Inc., alleging that the TFN intramedullary nail infringes the '663 patent. On or about January 21, 2003, Smith & Nephew amended its complaint to add Synthes (U.S.A.) as a party and alleged that Synthes (U.S.A.)'s making, using, offering to sell and selling of the TFN intramedullary nail infringes the '663 patent.

19. Admits as to paragraph 51 that a justiciable controversy exists between Synthes (U.S.A.) and Smith & Nephew as to the rights of Synthes (U.S.A.) to continue to manufacture, use, offer for sale, sell, or import its TFN intramedullary nail, related systems and other similar devices in the United States in view of its infringement of Smith & Nephew's valid and enforceable '663 patent.

20. Denies the allegations set forth in paragraph 52.

21. Denies the allegations set forth in paragraph 53.

FIRST AFFIRMATIVE DEFENSE

Synthes (U.S.A.)'s counterclaims fail, in whole or in part, to state a claim upon which relief may be granted.

WHEREFORE, Smith & Nephew prays that Synthes (U.S.A.)'s counterclaims be dismissed and that costs and attorney fees be awarded to Smith & Nephew; and that Smith & Nephew has the relief prayed for in its complaint together with such other and further relief as the Court may deem just.

Dated: March 12, 2004

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFF
SMITH & NEPHEW, INC.

CERTIFICATE OF SERVICE

The undersigned attorney for Plaintiff Smith & Nephew, Inc. hereby certifies that a copy of the foregoing Smith & Nephew's Reply to Synthes (U.S.A.)'s Counterclaims was duly served on all defendants in this action, on March 12, 2004, by delivery to the following by the method indicated:

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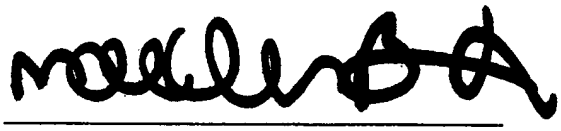


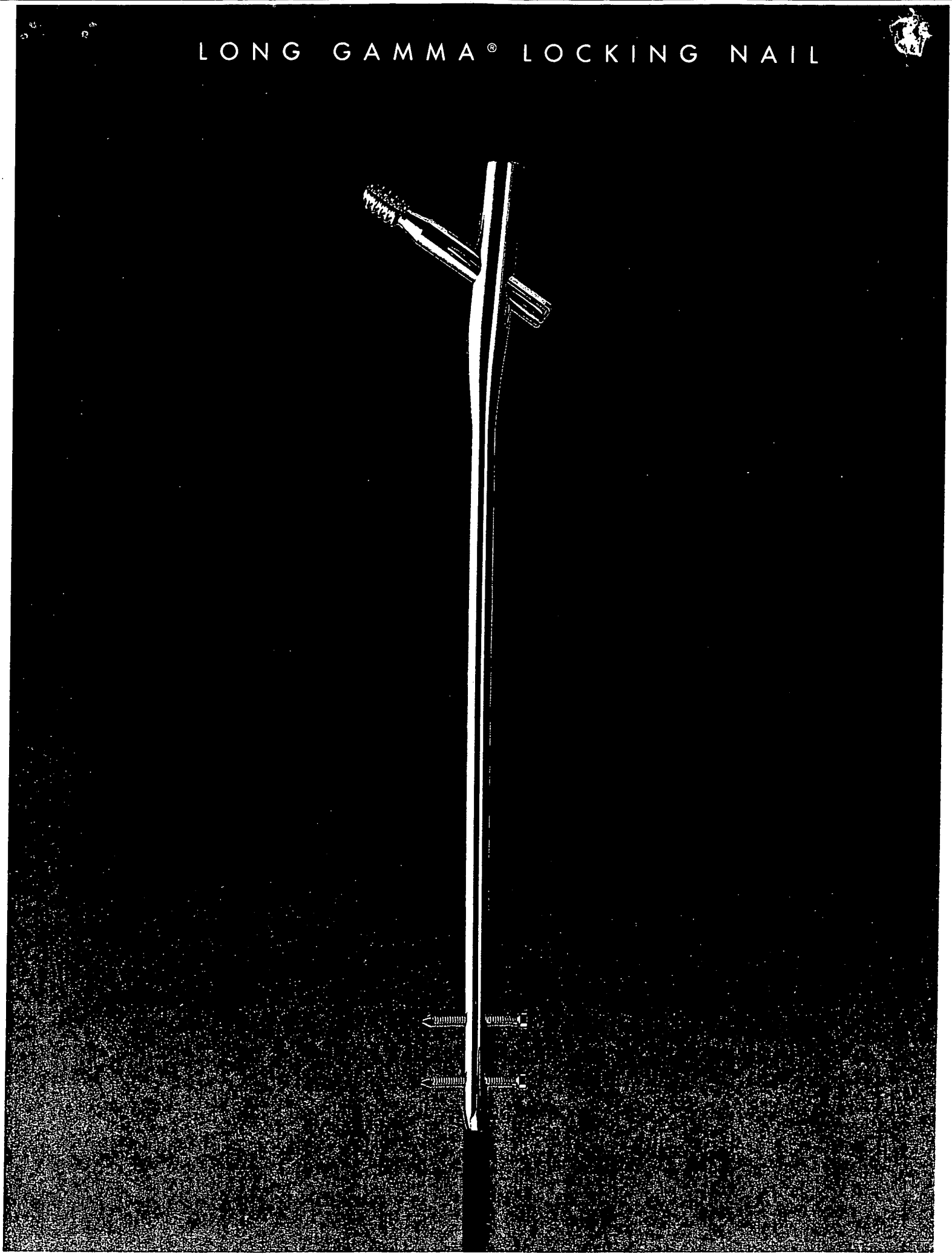
Mark Vorder-Bruegge, Jr.

LONG GAMMA® LOCKING NAIL

Surgical technique for femoral fracture fixation

Operating Guide

LONG GAMMA® LOCKING NAIL



CONTENTS

This publication sets forth detailed recommended procedures for using Howmedica Osteonics devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Acknowledgements:

The Gamma® Locking Nail Operating Technique was compiled from the kind contributions of leading surgeons in many countries; the principal authors and commentators were:-

Dr. G. Taglang, Dr. A. Grosse, Strasbourg, France
Dr. S.C. Halder, Halifax, UK
Dr K.S. Leung, Hong Kong
Dr. S. Boriani, Bologna, Italy

Our thanks are due to the many surgeons whose work has helped to confirm the utility of the technique to present and future users of the Gamma® Locking Nail family.

Warning:

Bone screws referenced in this material are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

THE DEVELOPMENT OF THE LONG GAMMA® LOCKING NAIL

The Long Gamma® Locking Nail is a specialized development of the original Gamma® Locking Nail. Howmedica Osteonics introduced the Long variant entirely in response to demand from experienced surgeons worldwide who wished to extend the benefits of the highly successful standard Gamma Nail to even more patients.

Long nails

Following the world-wide introduction of the Gamma® Locking Nail, experienced surgeons regularly requested long variants from Howmedica Osteonics to deal with certain specific clinical challenges. Versions with extended distal stems were requested for such indications as:-

- **Spiralling subtrochanteric fractures**
- **Ipsilateral neck and shaft fractures**
- **Prophylactic use – to avoid pathologic fractures in osteoporotic bones in both trochanteric and diaphyseal areas**

For such applications, the advantages of using an intramedullary locking nail in proximal fractures were now extended for more distal fractures, i.e. increased security of fixation, optimum biomechanical advantage, closed operating technique and flexibility of locking options to provide control of fracture fragments and allow dynamization. The same benefits of early weight-bearing and rapid rehabilitation, even in complex fractures, led more and more surgeons to request these speciality implants.

Long Gamma Nail introduction

After more than five years' experience with these speciality implants in Europe, Howmedica Osteonics introduced the Long Gamma® Locking Nail as a standard implant to satisfy the continuing demand for this specialized variant. Intended for use by experienced surgeons already familiar with the operating technique for the standard Gamma® Locking Nail, the Long Gamma® Locking Nail was introduced in a range of four lengths and three angles, handed left and right. The success of the Long Gamma® Locking Nail has completely justified its introduction, with tens of thousands of implants supplied worldwide since launch.

Clinical pedigree

Published clinical studies for the Gamma® Locking Nail family are among the most extensive for any surgical implant currently available. They consistently illustrate how successfully this evolving range of implants has achieved the original design goals: to improve both the procedure and prognosis for all grades of femoral fracture by extending the application of the established intramedullary principle to set a new standard for treatment:

- **Early weight-bearing[1,2,3,4,5,6,7] through superior strength and stability**
- **Reduced trauma[3,4] through closed operating technique[3,4]**
- **Low blood loss[5,6], low level of wound problems[5] and low risk of infection[5]**
- **More secure fracture fixation through better biomechanics[7]**

The clinical objective of the Long Gamma® Locking Nail, as with the recently introduced Trochanteric Gamma® Locking Nail, is:

Rapid mobilization, with fewer complications, for better patient rehabilitation[7]

The operating technique for the Long Gamma® Locking Nail is essentially the same as for the standard Gamma® Locking Nail, the main variation being in the distal locking process. The Long Gamma® Nail uses the same award-winning instrumentation* as for the rest of the Gamma® family, obviating the need for further inventory and training for both the surgeon and the surgical team.

While the Long Gamma® Nail is indicated in relatively infrequent clinical situations, Howmedica Osteonics believes that the value of this implant as a surgical option is significant in respect of the potential patient benefits; reduced surgical trauma and early weight-bearing are both important contributors to rapid mobilization and successful recovery from fracture.

If you have any difficulties with the technique, or questions about the Long Gamma® Locking Nail, please contact your local Howmedica Osteonics representative.

* Design-Innovation '95, awarded for high design quality; Design Centre, Nordrhein Westfalen.

REFERENCES:

1. Grosse A., Favreul E., Taglang G., "The Gamma® Nail; The results at the CTO Strasbourg" Paper presented at the International Symposium "Recent Advances in Locking Nails", Hong Kong, 1992.

2. Taglang G., Favreul E., "Results from the Centre de Traumatologie et d'Orthopédie, Strasbourg": Paper presented at the Advanced Course in Intramedullary Locking Nailing, Courchevel, France, February 1991.

3. Leung K.S. et al, (Prince of Wales Hospital, Hong Kong), J Bone Joint Surg [Br] 1992; **74B**, 3:345-51.

4. Boriani S. et al., results of Multicentric Italian Experience on the Gamma® Nail. A report on 648 cases, Orthopedics 1991;**14**,12: 1307-1314.

5. Radford P.J., (University Hospital Queen's Medical Centre, Nottingham, England): "Comparison of results of the Gamma® Nail and Dynamic Hip Screw in Extracapsular fractures of the Proximal Femur.": Paper presented at Advanced Course in Intramedullary Locking Nailing, Courchevel, France, February 1991.

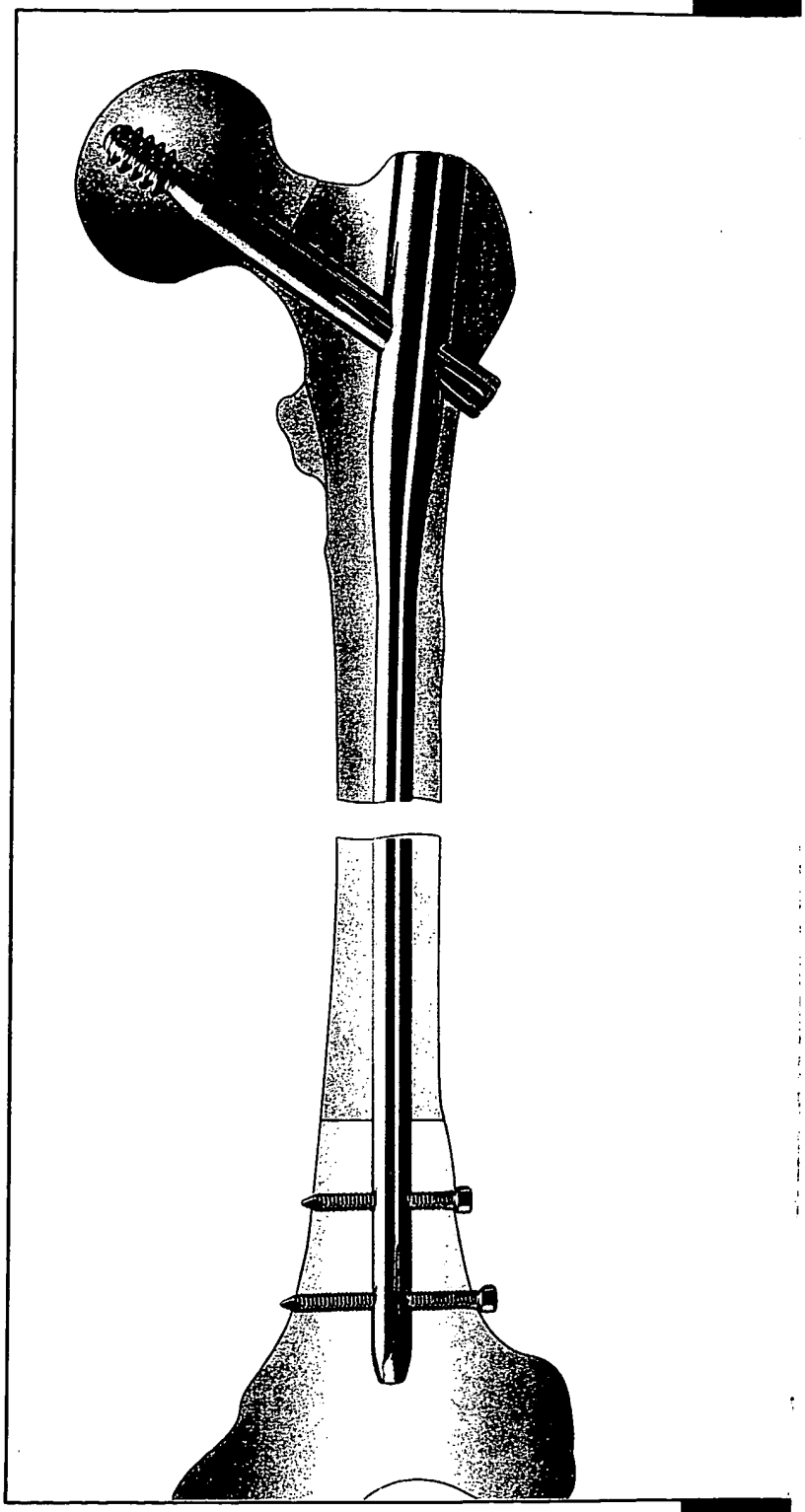
6. Williams J.J., Cohen P.Z., Pittsburgh Orthopaedic Journal, 1990, Volume 1, pages 20 - 23.

7. De Groote W., Van Hoye M. et al, (St Jan General Hospital, Bruge/Middelheim General Hospital, Antwerp, Belgium): "The Gamma® Locking Nail in the treatment of Long fractures" Article in press.

Indications

- Unstable intertrochanteric fractures
- Subtrochanteric fractures
- Ipsilateral intertrochanteric and femoral shaft fractures.
- Pathologic and impending pathologic fractures within the trochanteric and diaphyseal areas of the femur.
- Proximal or distal non-unions and mal-unions, revision procedures.

X-ray illustrations of a range of Long Gamma® Locking Nail uses are shown on the inside back cover of this guide



Anatomical efficiency

The Long Gamma® Locking Nail is designed for optimum efficiency both in operating technique and subsequent rehabilitation, effective in a wide range of clinical situations and fracture complexity. Insertion is entirely by closed surgical technique, minimizing soft tissue trauma, blood loss and infection potential.

The Nail

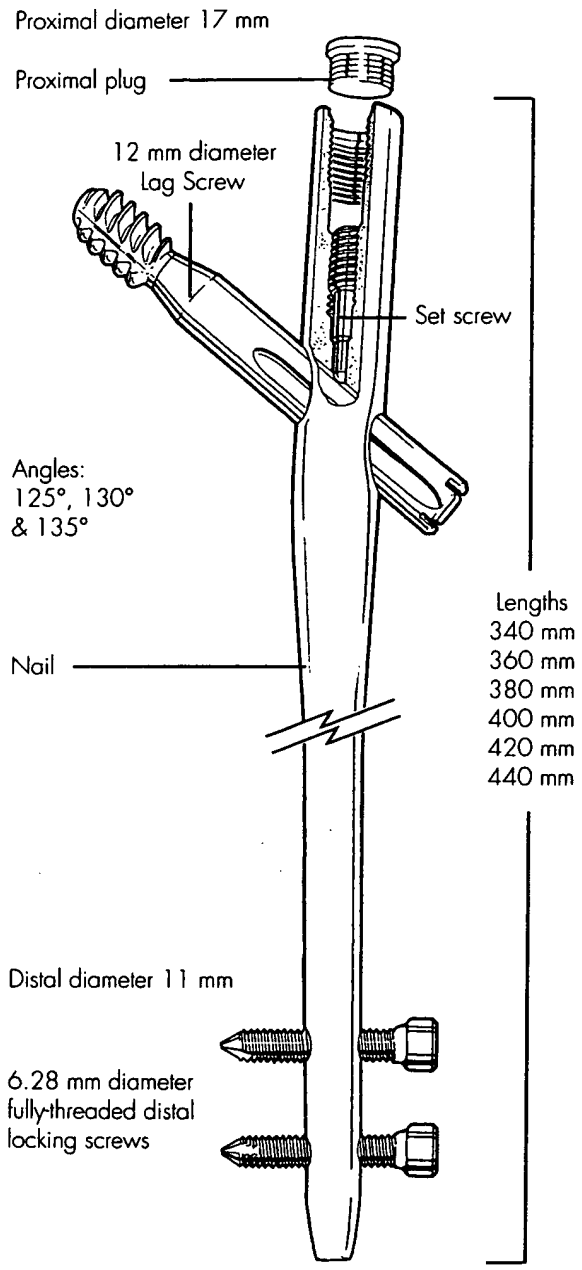
The nail incorporates several important mechanical design features. It is unslotted and cannulated for guide wire controlled insertion. It has a 17 mm proximal diameter tapering to 11 mm distally and is available in Left and Right forms in lengths from 340 mm to 440 mm in 20 mm steps. Variations in femoral neck anatomy are accommodated by a range of neck angles available for the lag screw entry (125°, 130°, 135°). The nail incorporates proximal lateral bend of 4° and anteversion of 10°. Two distal locking screws are inserted through the distal end of the nail to control rotation and telescoping.

The Lag Screw

The lag screw, inserted through a small incision with the aid of a radiolucent targeting device, incorporates a special sliding lock to provide dynamic compression with axial stability. After insertion, a set screw inserted through the proximal head of the nail engages in one of four grooves in the lag screw. As these are of asymmetrical depth profile, they allow the lag screw to slide in one direction, producing dynamic osteosynthesis by compression during early weight-bearing. The lag screw incorporates a rounded nose profile and self-tapping thread designed for easy insertion and resistance to cut-out.

Instrumentation

All instruments are the same as for the Trochanteric Gamma® Locking Nail, except that distal targeting is accomplished using a free-hand technique.



The Gamma® advantage – strength and stability

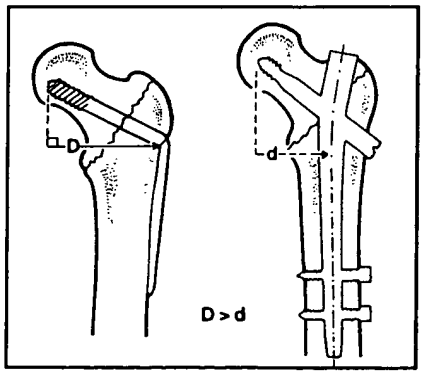
The Long Gamma® Locking Nail offers great strength and stability in clinical use through the inherent biomechanical advantage of the intramedullary system.

The biomechanical advantage

As the load-bearing axis of the Long Gamma® Locking Nail is closer to the hip joint fulcrum, the effective lever on the implant and femur is significantly less than with an external plate, reduced by a factor equivalent to d/D in the diagram (approximately 25%*). The resultant force is transmitted directly down the center of the femur rather than through the many bone-weakening screws used in the side-plate system, increasing both the strength and reliability of the mechanical repair.

The rehabilitation advantage

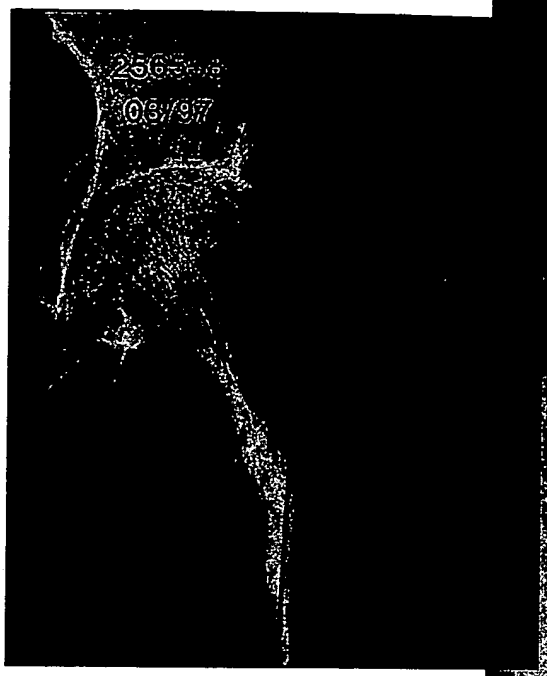
The extra strength effectively gained by the biomechanical advantage of the Long Gamma® Locking Nail, combined with improved control of axial telescoping and rotational instability, allows early weight-bearing even in complex or unstable proximal fractures. Earlier mobilization, combined with dynamic compression and less traumatic operative technique, increases the chance of successful patient recovery and reliable repair.



* Leung K.S., The Chinese University of Hong Kong: Gamma® AP Anthropometric Study of Proximal Femur, Jan 1991; Data on file, Howmedica Osteonics.

This surgical technique has been devised in consultation with leading surgeons in many countries to be a basic guide, particularly for less experienced users of the Long Gamma® Locking Nail. It is acknowledged that several alternative approaches to certain elements of the procedure are practiced, and may have advantages for particular situations or surgeons. Parts of this guide may seem simplistic or redundant for experienced users, but are included for the guidance of more junior staff.

A chart of the complete operating instrumentation is folded into the back of this Operating Guide, and can be folded out for easy reference. Each instrument is keyed to the chart by a reference number.



Pre-operative planning

In the majority of patients the standard 130° neck angle can be used without difficulty. The 125° neck angle may be needed in osteoarthritic coxa vara, and the 135° in coxa valga. Where such variations in femoral anatomy require an alternative, the following method may be used to confirm the nail angle selection.

Determination of neck angle

A true anterior-posterior (A-P) pre-operative X-ray is required. This can either be taken from the fractured hip, if an accurate anatomical reduction has been obtained, or from the contralateral hip. Check the femoral neck angle, i.e. the angle between the femoral shaft mid-axis and the femoral neck mid-axis, using a goniometer as shown.

Nail length selection

The appropriate length of Long Gamma Locking Nail can be chosen either by pre-operative planning using an X-ray of the injured femur, or per-operatively as is the usual practice in intramedullary nailing.

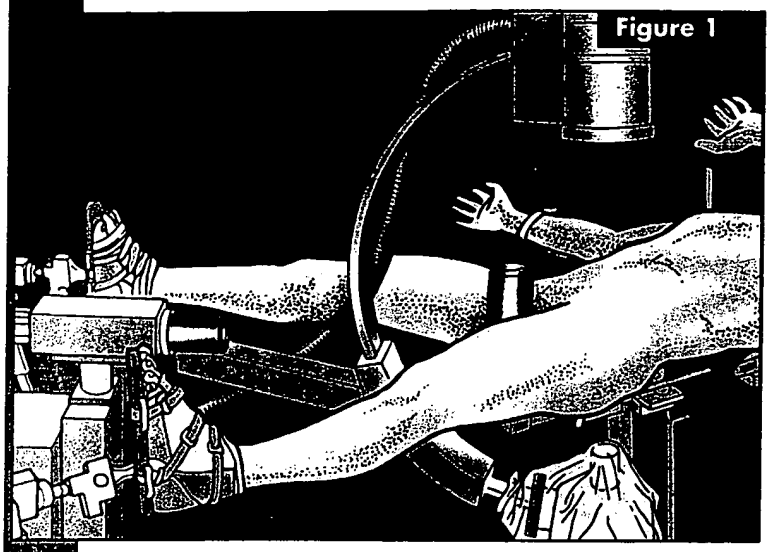


Figure 1

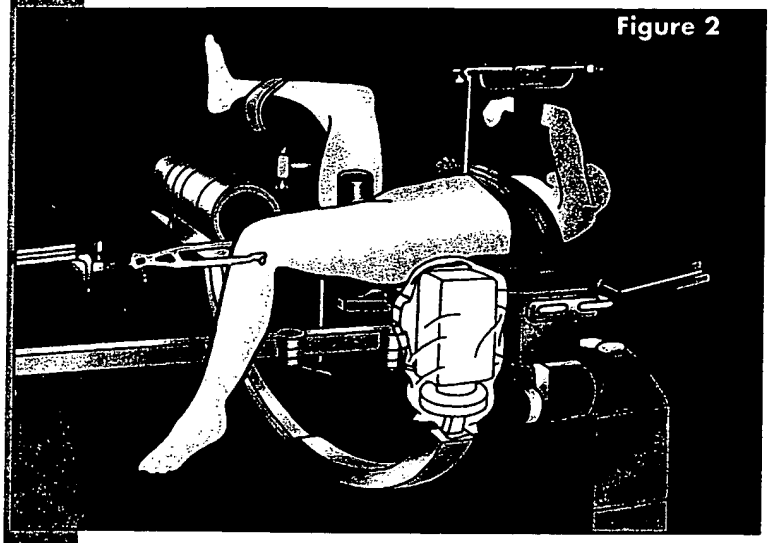


Figure 2

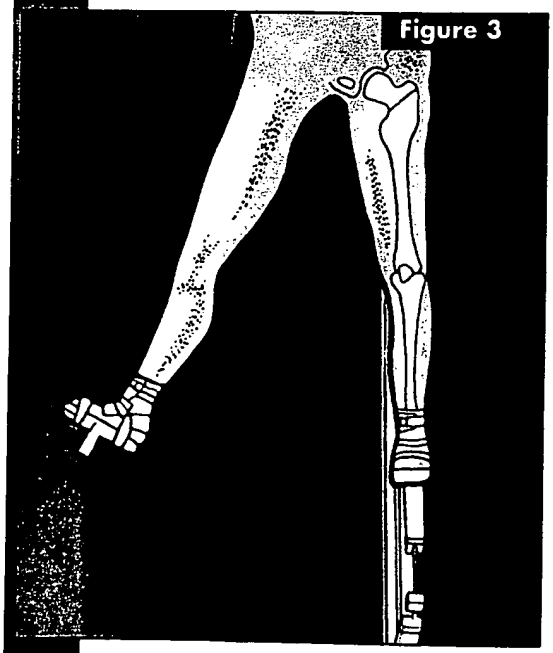


Figure 3

The procedure for patient positioning is normally the same as for the standard Gamma (Figure 1); however, in fractures that are particularly difficult to reduce, a transcondylar sterile Steinmann pin may be used. The pin is fixed directly to the orthopaedic table by an adaptable stirrup, and traction is applied until anatomical reduction in the A-P view is obtained (Figure 2).

Image intensifier positioning

The image intensifier is positioned so that anterior-posterior and medio-lateral views of the trochanteric region of the affected femur can be easily obtained. This position is best achieved if the image intensifier can be positioned so that the axis of rotation of the intensifier is centered on the femoral neck of the affected femur (Figure 1).

Fracture reduction

For specific situations, special techniques have been developed to aid successful fracture reduction, and these are explained below. In general, however, the patient is placed in a supine position on the fracture table and closed reduction of the fracture is obtained as shown in figure 3.

Traction is applied to the fracture, keeping the leg straight. Maintaining the traction, the leg is internally rotated 10 - 15 degrees to complete the reduction of the fracture; the patella should then be either horizontal or slightly internally rotated.

IMPORTANT
Reduction should be achieved as anatomically as possible. If this is not achievable, reduction in one plane should be achieved, leaving reduction in the other plane to be achieved with the Long Gamma® Locking Nail during insertion.

The unaffected leg is abducted as far as possible in order to accommodate the image intensifier. The patient is then prepared and draped as for standard hip fracture fixation, but bear in mind that the incision is rather more proximal when positioning the drapes.

Proximal fractures

This type of fracture can be difficult to reduce because the proximal fragment is in flexion due to the pull of the psoas muscles, while the distal portion is in varus position due to the pull of the adductor muscles (Figure 4).

To counter this mis-alignment, the trunk is bent to the opposite side and maintained by a thoracic rest or by a large drape. This extends the gluteus medius muscles, externally rotating the proximal fragment into alignment and exposing the trochanter for easier introduction of the nail (Figure 5). The fractured limb is kept straight with the knee in flexion (Figure 5), using the stirrup to avoid adduction. This positioning externally rotates the distal portion. Reduction is confirmed on the AP view.

Sub-trochanteric fractures cannot always be reduced during positioning on the lateral view, because the proximal fragment is drawn forward by the pull of the psoas muscles. They must be reduced during the operation by means of the special repositioning guide from the G & K system miscellaneous tray. (Figure 6)

Care must be taken when introducing the implant, as the proximal fragment may rotate during insertion; the locking nail must be carefully introduced exactly into the tip of the greater trochanter, as far as possible by hand.

Anteversion guide insertion

With the image intensifier C-arm in the horizontal position to give the lateral view of the femoral neck and head, a 2 mm Kirschner wire is inserted percutaneously, anterior to the shaft and parallel to the axis of the femoral neck and head. This is to provide a guide to the angle of anteversion of the femoral neck during later insertion of the nail, during which the targeting device is kept parallel to the Kirschner wire in the coronal plane (Figure 7).

Alternatively, the guide wire can be inserted after the lag screw guide sleeve is placed in position (see page 14).


Figure 4


Figure 5

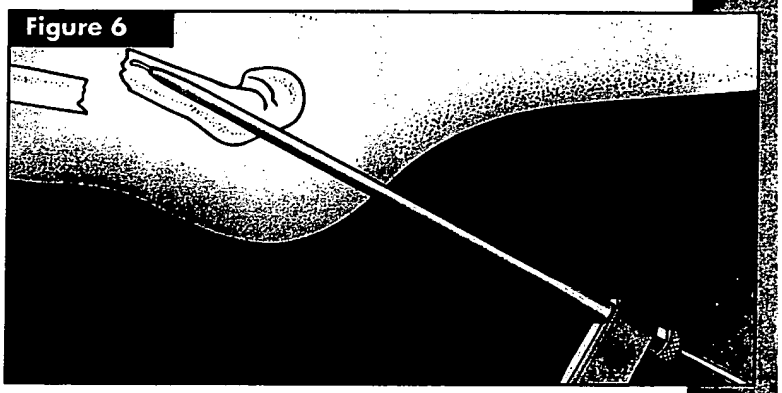


Figure 6

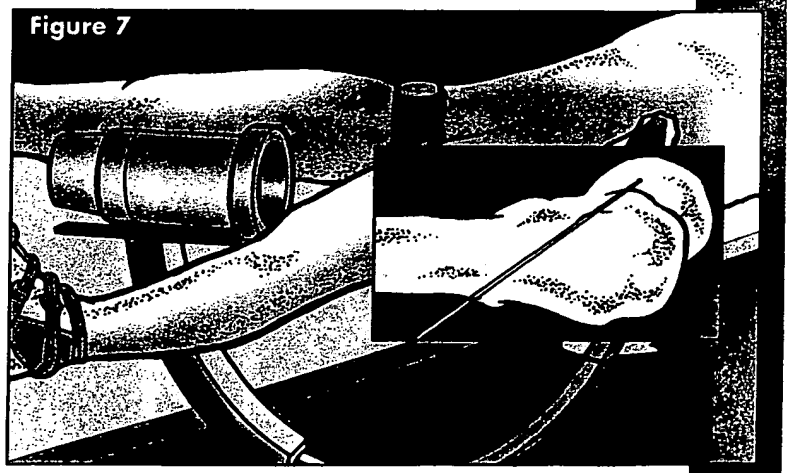
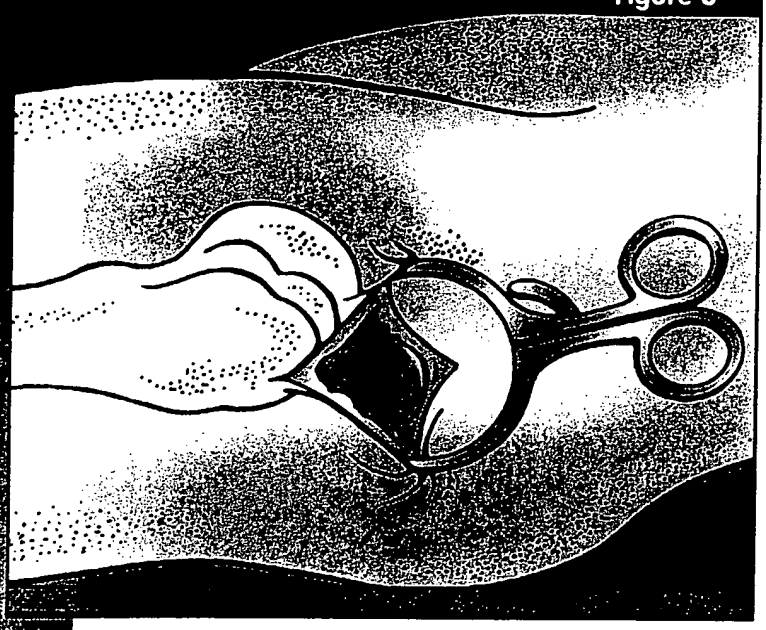


Figure 7

Figure 8



INCISION

Determination of the soft tissue incision position

With experience, the tip of the greater trochanter can be located by palpation, and a horizontal skin incision of approximately 5 cm is made from the greater trochanter to the iliac crest. The incision is deepened through the fascia lata, splitting the abductor muscle for approximately 3 cm immediately above the tip of the greater trochanter, thus exposing its tip. A self-retractor is put in place (Figure 8).

ENTRY POINT

Finding the bone entry point

The correct entry point can be identified by touch; it is located at the junction of the anterior third and posterior two-thirds of the tip of the greater trochanter and on the tip itself.

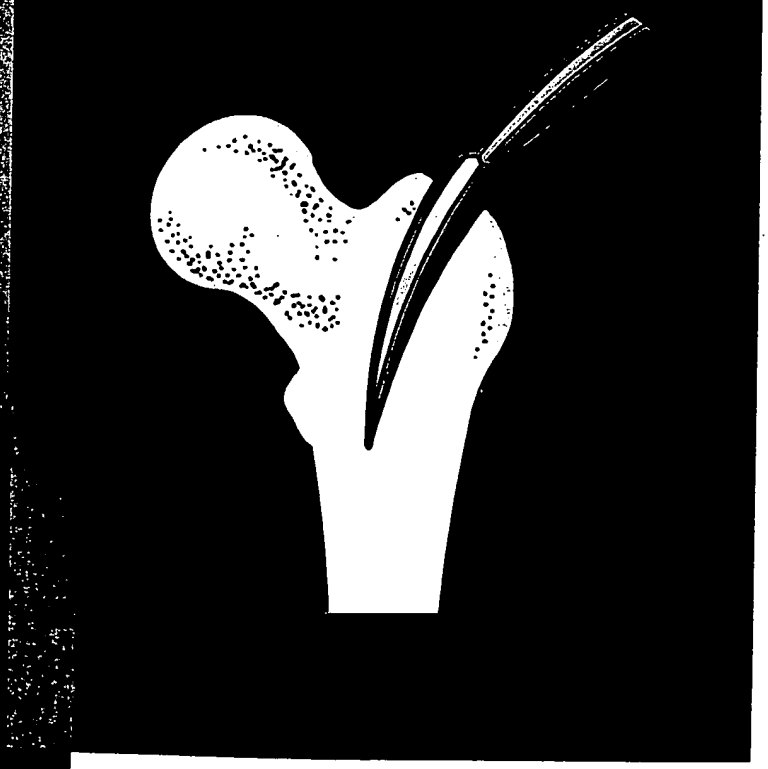
Breaching the cortex

The medullary canal is opened under image intensification using the reverse curved awl (1). Care must be taken to ensure that the awl is not misplaced; this is more likely in the anterior-posterior plane i.e. as seen on the lateral view.

The insertion point should be just on the tip of the greater trochanter. If it is very medial (e.g. in the piriform fossa) the nail will not go down the shaft properly, with the danger of fracturing the femur.

When the entry point has been made, the reamer guide wire is placed in position so that the proximal femur may be prepared using flexible intramedullary reamers (Figure 9).

Figure 9



PREPARATION OF THE MEDULLARY CAVITY

In order to accommodate the proximal end of the Long Gamma® Locking Nail, the trochanteric region MUST be reamed to 17 mm (Figure 10).

The whole femoral canal cavity must be at least 2 mm greater than the distal diameter of the nail i.e. at least 13 mm; reaming may be necessary in some patients to achieve this.

REAMING TECHNIQUE

A pre-curved guide wire is passed through the fracture site, the head of the guide wire being centered in the distal epiphysis.

Pass the reamer guide wire from the tip of the greater trochanter into the shaft of the femur as shown in Figure 11, using the Jacob's chuck (2). Rotating the guide wire during insertion will help it to take up the desired position and avoid it coming out of a posterior fracture line.

Flexible reamers are used to ream the shaft of the femur in stages starting from 9 mm diameter and increasing in 0.5 mm increments (Figure 12), to a minimum of 13 mm. Reaming is continued until the reamer starts to bite/catch the endosteal surface. A-P as well as lateral control of the reamer is necessary. Where there is comminuted bone, reaming should be stopped at the fracture site, penetration continued past the comminuted site with the power drill off, then power reaming continued.

Use of the skin protector (3) during intramedullary reaming is recommended. Care must be taken with flexible reamers to ensure that the guide wire is not displaced laterally during reaming. This could lead to resection of more bone on the lateral side of the wire, which in turn would lead to an offset position for the nail and a risk of fracturing the shaft.

NOTE: The Gamma® blunt tip reamer guide wire is recommended for use in reaming and nail insertion. The blunt end is designed to pass easily through the nail cannulation, eliminating the need for guide wire exchange.

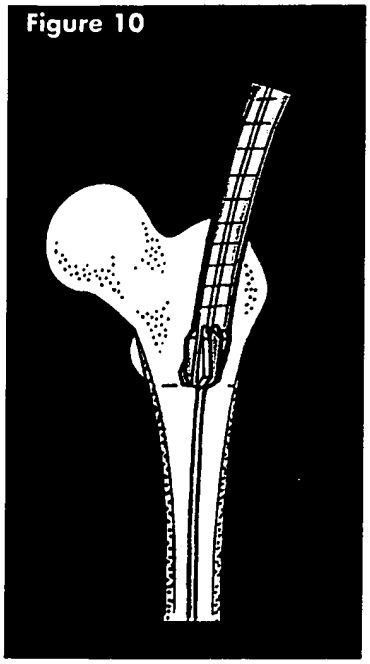


Figure 10

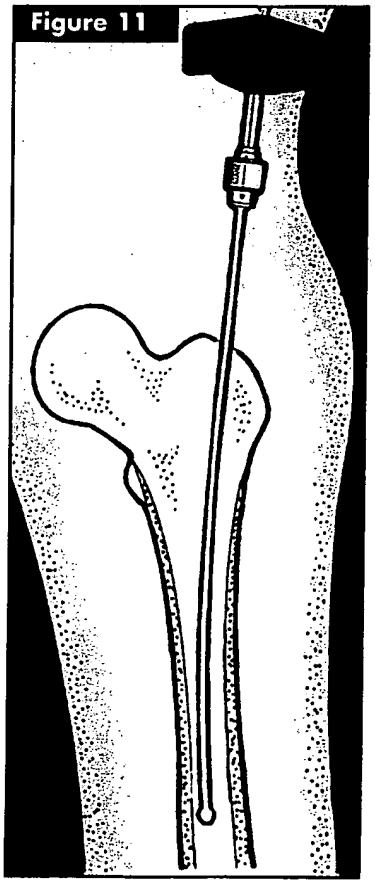


Figure 11

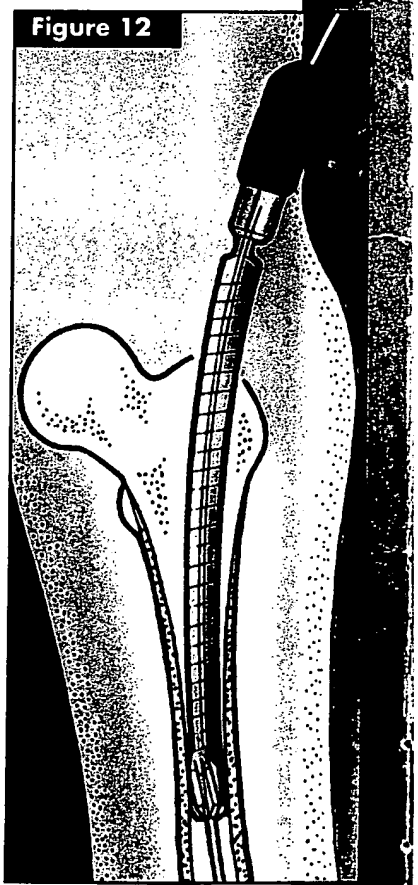


Figure 12

Figure 13

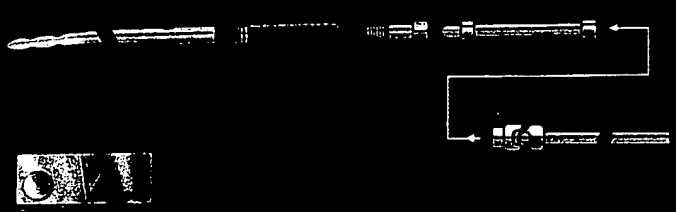
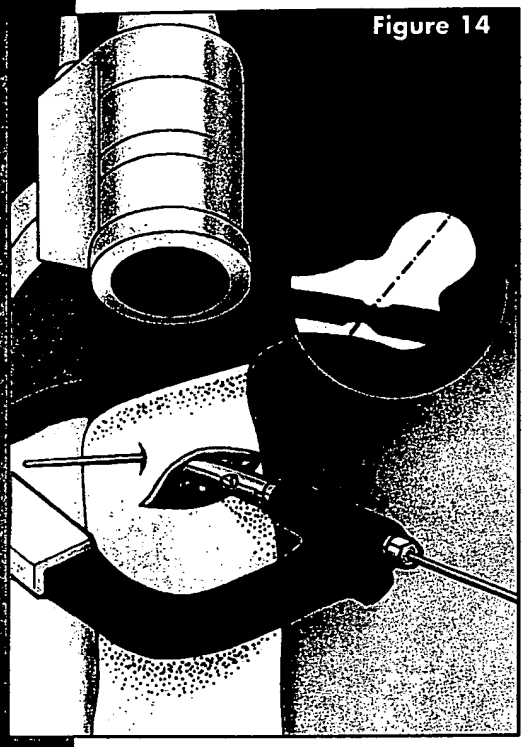


Figure 14



*** NOTE: It is sometimes difficult to fully insert the nail into the femur; one reason could be that the medullary canal is too narrow. As the Long Gamma® Locking Nail is a very strong, rigid implant, it should not be forced into the femur e.g. by hammering, as there is a danger of fracturing the femur. If the nail will not go into the femoral cavity far enough to allow correct positioning of the lag screw, further reaming should be carried out in 0.5 mm increments until the nail will go in fully.**

NAIL INSERTION

Assembly of the targeting device

The selected nail is now assembled onto the carbon fiber targeting device (5) as shown in Figure 13, ensuring that the locating peg slots into the corresponding notch; it is held by the nail holding bolt (4), and tightened using the socket wrench (7) and nail holding bolt screwdriver (6).

Nail/Lag Screw Positioning

Nail insertion is monitored with the image intensifier C-arm; **the projected axis of the lag screw should be measured with a ruler on the monitor screen** to ensure that the lag screw will be positioned in the ideal position. **Visual estimation has proved to be unreliable.** To ensure correct positioning of the lag screw, close attention must be given to the anteversion angle and to the depth of insertion of the nail into the femoral canal.

Using anterior-posterior screening, the Long Gamma® Locking Nail is inserted by hand **(TAKE CARE TO AVOID UNDUE FORCE – DO NOT USE A HAMMER *)** until the axis of the lag screw hole (visible as crescent shapes on the screen) is lined up with the inferior half of the femoral neck. The desired result of this is to ultimately position the lag screw tip just **below** the center of the femoral **head** in the frontal plane (see Figure 19). Note that the additional length of the Long Gamma® Nail may, in a small number of cases, necessitate impaction for the final 2-3 cms of insertion with the **final impactor (8)** supplied. This should be carried out with extreme care; if any undue resistance is detected, the nail should be withdrawn and further reaming carried out.

CHECK: When the Long Gamma® Locking Nail is inserted to its final depth the plane of the targeting device will be parallel to the percutaneous guide wire positioned earlier (see page 10). This ensures the correct degree of rotation to align the lag screw holes with the angle of anteversion of the femoral neck.

LAG SCREW TARGETING

Remove the reaming guide wire using the Jacob's chuck (2), ensuring that the targeting device (5) is supported to prevent rotational movement of the Long Gamma® Nail. With the nail now inserted to the correct depth, slide the targeting sleeve (9) corresponding to the nail angle of the selected Long Gamma® Locking Nail onto the end of the targeting device (5) (Figure 15). **Please ensure before proceeding that the nail holding bolt (4) is fully tightened.**

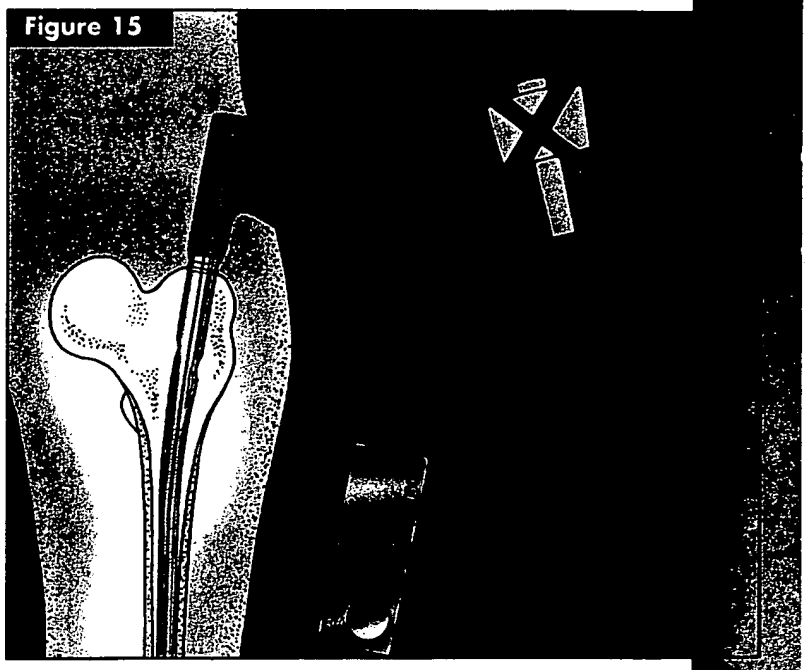
The targeting device (5) may require support by an assistant, to prevent its weight from externally rotating the nail, until the next stage is completed.

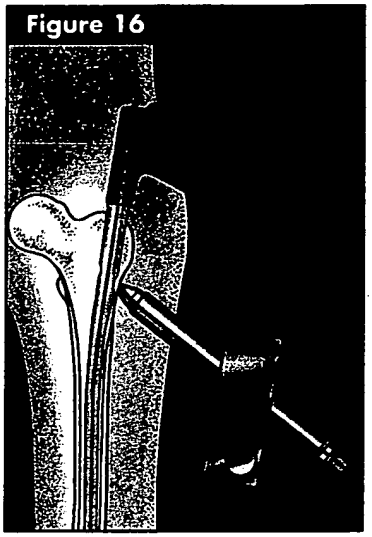
Next, assemble the Kirschner wire guide sleeve (10) and the guide sleeve for the lag screw (11), and pass them through the targeting sleeve (9) to the level of the skin. This now indicates the position for the small incision to be made, which is developed down to the bone.

The guide sleeve assembly is now passed through the incision to press firmly against the lateral cortex (Figure 16). If the guide catches the fascia lata, twisting it will usually allow it to pass through to the bone.

If not already inserted, the percutaneous anteversion guide should now be placed (see page 10).

The Kirschner wire guide sleeve (10) is removed and the lag screw guide sleeve (11) is firmly abutted to the lateral cortex of the femur to stabilize the targeting device (Figure 17). The thumbwheel on the targeting sleeve (9) should be tightened to lock the lag screw guide sleeve (11) in place and further stabilize the targeting assembly (Figure 17 inset).





LAG SCREW TARGETING

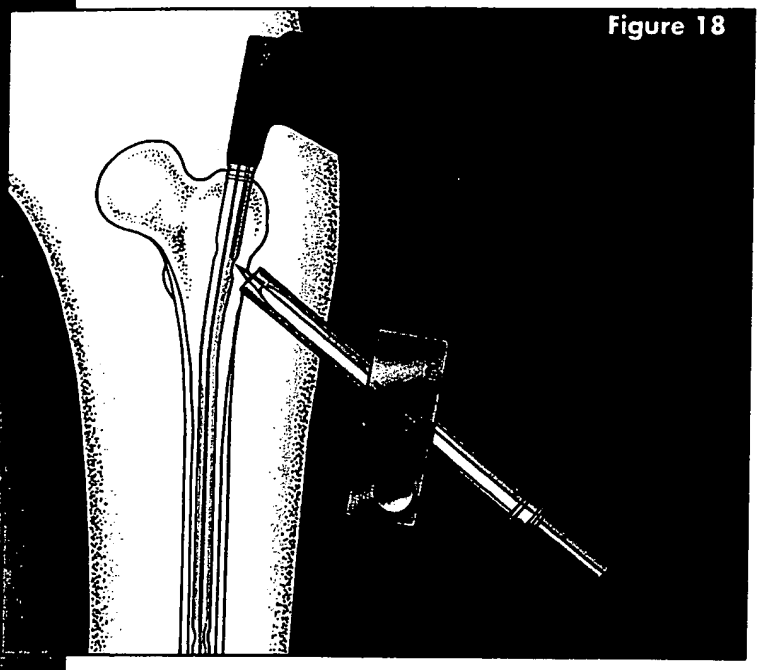


Figure 18

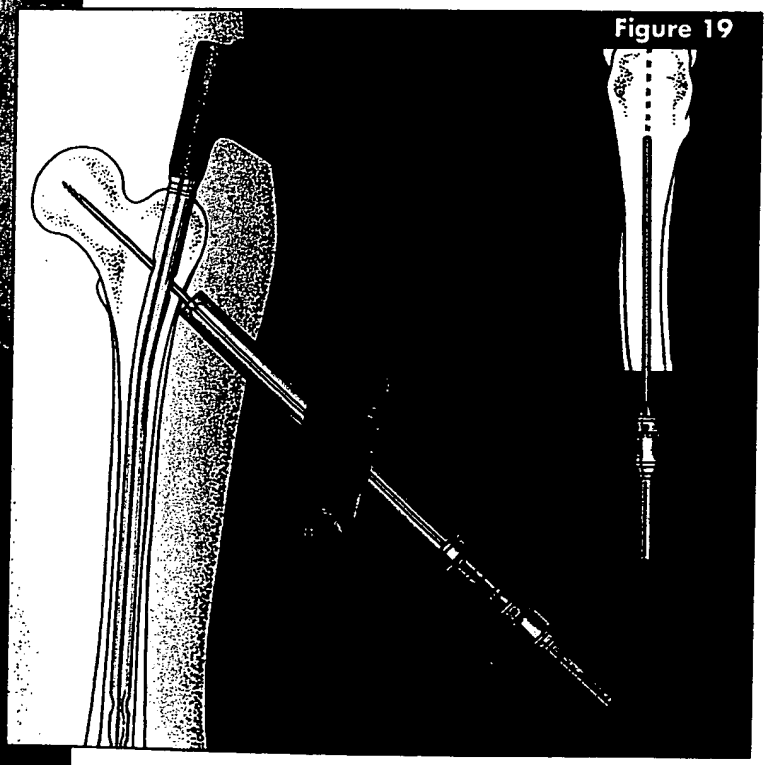


Figure 19

With the lag screw guide sleeve (9) firmly engaged in the cortex, the awl (12) should be inserted and turned by hand in order to pierce the lateral cortex (Figure18). Check for correct positioning on both anterior-posterior and lateral intensifier views.

NOTE: Before proceeding, check that the guide wire for the flexible reamer used earlier has been removed.

The Kirschner wire guide sleeve (10) is now re-inserted to act as a guide for the lag screw guide wire (13), which is inserted using the Jacob's chuck (2).

The guide wire should be screwed into the subchondral bone, checking for position on both the anterior-posterior and lateral intensifier views.

Checking is essential if you are to ensure good lag screw positioning. The tip of the guide wire (13) must be placed in the inferior half of the femoral head in the frontal plane, and on the midline in the lateral plane. The objective is to place the lag screw below the centre of the femoral head on the anterior-posterior view and centrally on the lateral view, to decrease the risk of it cutting superiorly out of the femoral head. (see Figure 19).

If the guide wire (13) is too anterior or posterior it must be repositioned; this should seldom be necessary if the anteversion-guiding percutaneous wire has been inserted correctly (see page 10).

If the guide wire (13) is mispositioned, the first step is to withdraw the guide wire, and then to withdraw the nail. Rotate the nail in the appropriate direction and re-insert as before. The guide wire is then re-drilled and control screening is carried out as before.

NOTE: Final lag screw position and length is measured from the base of the thread located at the proximal end of the lag screw guide wire (11), *NOT THE TIP.* The lag screw length measuring gauge is designed to read from the base of the guide wire thread.

After achieving a satisfactory position for the guide wire (13), the lag screw length required is measured using the lag screw length gauge (14). Before starting to measure, ensure that the lag screw guide sleeve (11) is pressed firmly against the lateral cortex of the femur.

Take the measuring gauge (14) and place it directly under the guide wire (13) and against the Kirschner wire guide sleeve (10) as shown in Figures 20a & b.

The measurement on the gauge is now transferred to the adjustable stop on the lag screw step drill (15). It should be noted that the adjustable stop is positioned with the chosen length next to the stop on **the side towards the drill tip** (Figure 21a). The collar is used to lock the stop in position (Figure 21b).

NOTE: To ensure accurate lag screw length, the Kirschner wire guide sleeve (10) must remain in the lag screw guide sleeve (11), as shown in figure 20b, when measuring lag screw length.

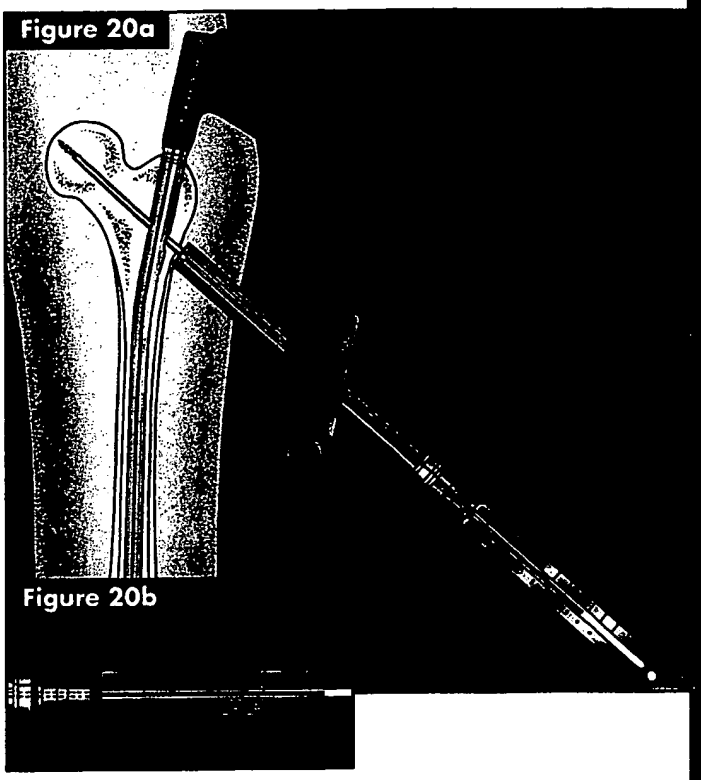


Figure 20a

Figure 20b

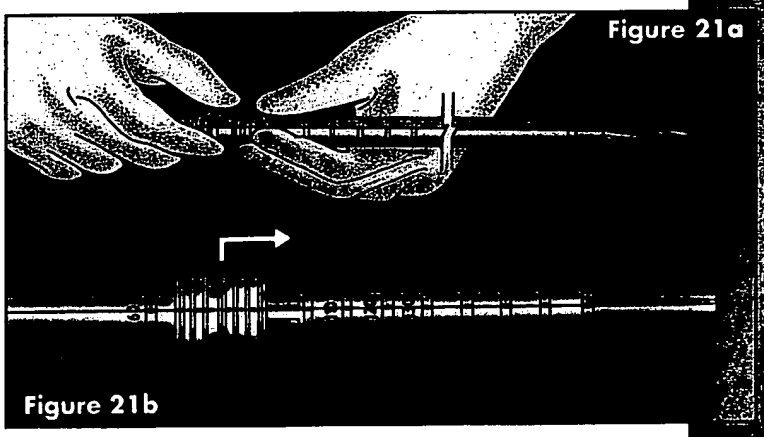


Figure 21a

Figure 21b

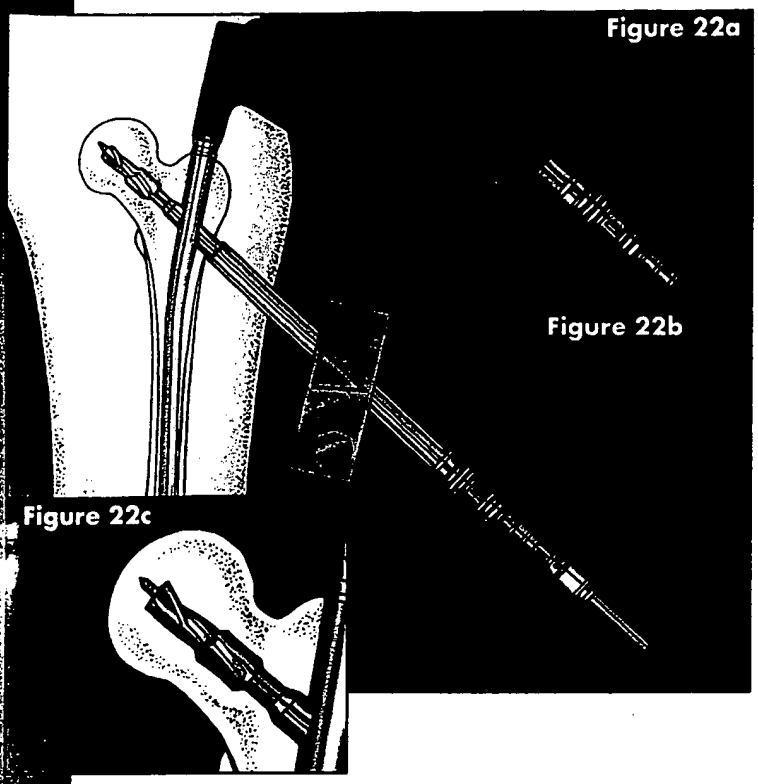


Figure 22a

Figure 22b

Figure 22c

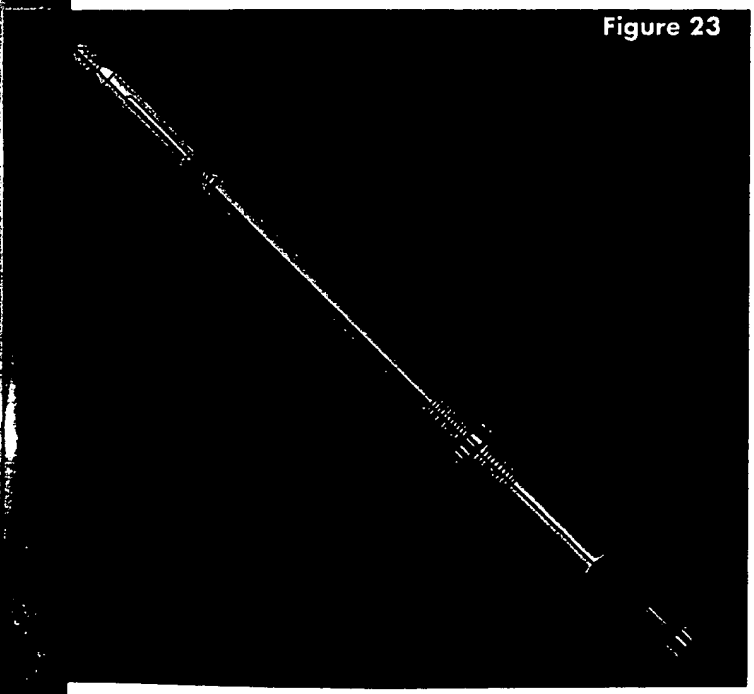


Figure 23

The Kirschner wire guide sleeve (10) is now removed and the lag screw step drill (15) is passed over the guide wire (13), through the lag screw guide sleeve (11) (see Figure 22a). The path for the lag screw is drilled using the Jacob's chuck (2). If exceptional resistance is encountered, a power drill may be used with **great care**. Drilling should continue until the stop impacts against the lag screw guide sleeve (see Figure 22b), **ensuring that the targeting device is well supported to prevent backing out and rotation.**

If you check on the image intensifier at this stage you should see the tip of the guide wire protruding slightly from the step drill (Figure 22c). This is because the threaded portion of the guide wire is deliberately excluded from the drill measurement to prevent joint penetration by the drill.

In patients with hard bone, the use of the lag screw tap (16) may be necessary for lag screw insertion. The lag screw tap (16) is designed to be used with the Jacob's chuck (2) handle.

The correct length lag screw is chosen by selecting a size at least 5 mm longer than the measurement previously made on the lag screw gauge (14) for drilling (see Figure 16). **It is important that the lag screw protrudes at least 5 mm from the lateral femoral cortex** to retain rotational stability and to permit sliding.

The correct size lag screw is now assembled with the lag screwdriver (17). The end thumbwheel must be pulled back, and the screw and driver connected as shown (Figure 23).

After pulling back and connecting, the end thumbwheel is tightened to secure the connection.

The lag screw is now passed over the guide wire (13), through the lag screw guide sleeve (11), and threaded up to the sub-chondral part of the head (Figure 24). If the guide wire is inadvertently removed, then the screw may still be passed without it provided that the lag screw guide sleeve is still in contact with the cortex.

After tightening the screw ensure that the handle of the lag screwdriver (17) is either parallel or perpendicular to the targeting device (5) so that the set screw will engage in one of the four lag screw grooves (see Figure 25c).

SET SCREW INSERTION

The set screw is inserted through the opening in the carbon fiber targeting device (5) and the nail holding bolt (4) at the proximal end of the nail (Figure 25b). It is then tightened fully using the set screwdriver (18) and socket wrench (7). You may find this a little stiff because the screw has a nylon insert in the threads to prevent spontaneous loosening.

The screw should then be unscrewed one quarter of a turn to ensure free sliding of the lag screw. Ensure that the set screw is still engaged in the groove by checking that the lag screw cannot now be rotated with the lag screwdriver (17).

Check the final position of the implant using the image intensifier in the anterior-posterior and lateral planes (Figs 37a & b).

As distal locking of the Long Gamma Nail is not carried out using the carbon fiber targeting device, this should now be removed as follows: disconnect the lag screwdriver (17) using the end thumbwheel, remove the lag screwdriver (17), lag screw guide sleeve (11), guide wire (13), nail holding bolt (4), targeting device (5) and sleeve (9).

A proximal plug (see Fig 25c) is available to prevent ingrowth from becoming trapped in the proximal threads of the nail, this is tightened using the set screwdriver (18).

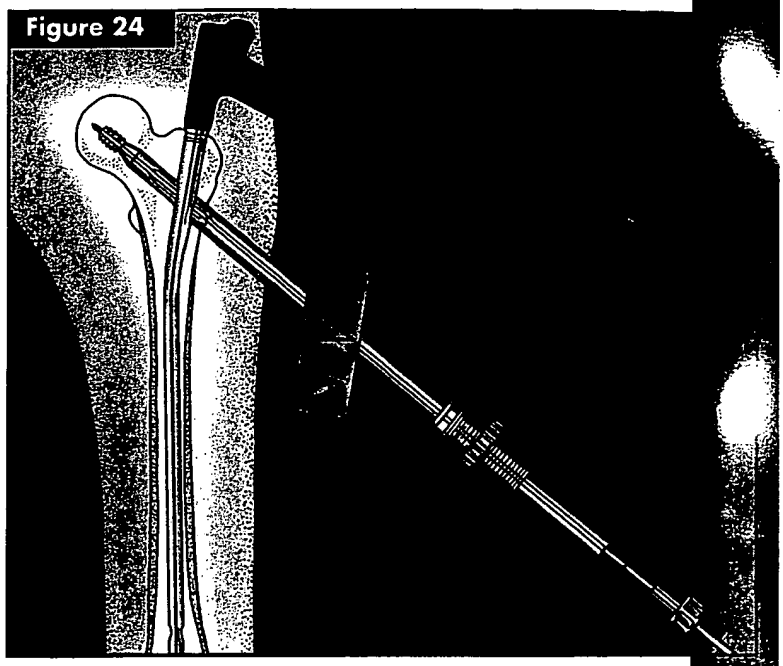


Figure 24

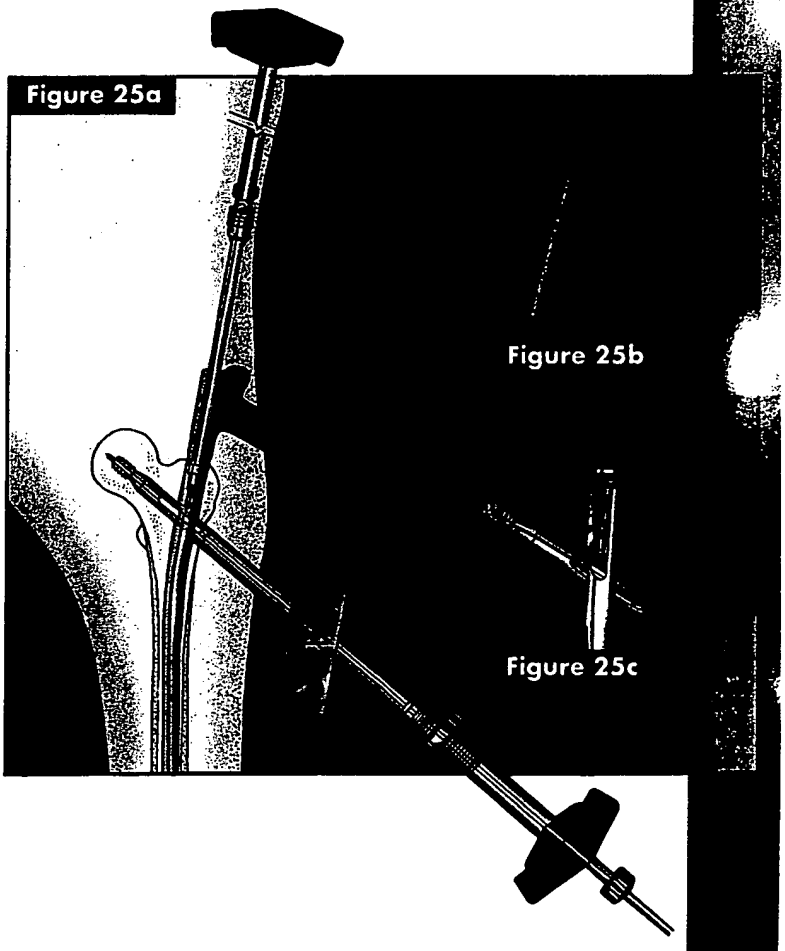


Figure 25a

Figure 25b

Figure 25c

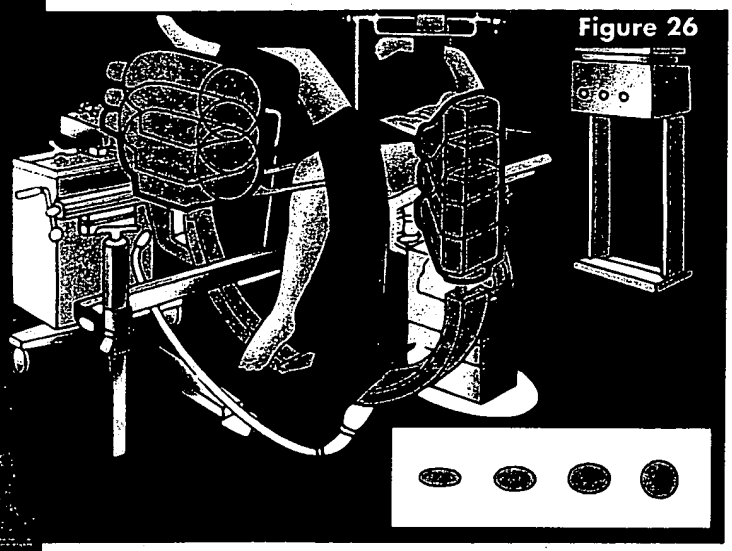


Figure 26

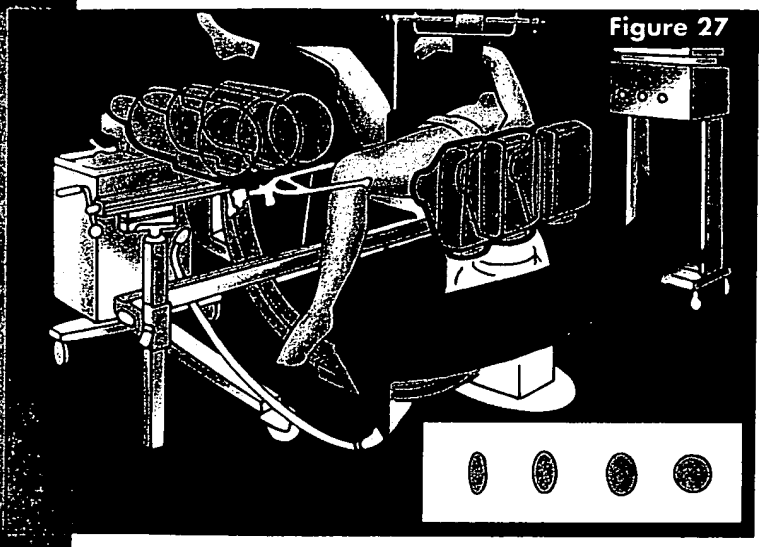


Figure 27

Distal Screw targeting

Various techniques can be used to guide drilling and insertion of screws through the distal holes. The method described here is the free-hand technique.

Sighting the distal holes

The essential initial step in distal targeting is to position the image intensifier so that the distal holes in the nail appear perfectly round. If the holes appear to be elliptical in either the vertical or horizontal planes, the image intensifier position must be adjusted appropriately as shown (Figures 26 and 27).

FREE-HAND TECHNIQUE

The Universal Free-hand Distal Targeting Device* from the G & K system miscellaneous tray is recommended.

The essential first step of using this device is to align the image intensifier with the most distal screw hole of the nail until a perfect circle is seen. A 4 mm Steinmann pin is passed through the free-hand device and, using the image intensifier, placed against the soft tissue to indicate the stab wound incision site.

After the incision is made, and with the image-intensifier on, use the free-hand device to place the Steinmann pin in the exact center of the visualized hole. Hold the point of the pin firmly against the proximal cortex (Figure 33).

With the pin stationary, move the device until both alignment rings appear as one and the pin appears to be a dot in the center of the single ring (Figure 34).

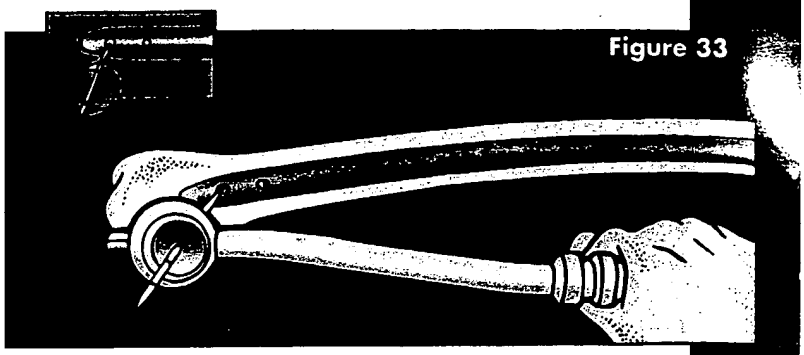


Figure 33

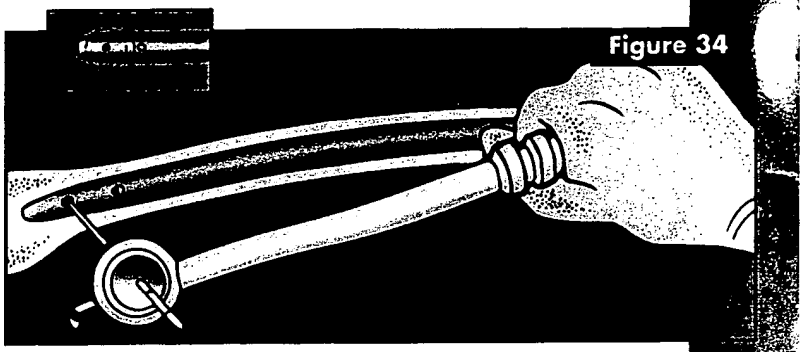


Figure 34

* Developed by Dr. D. Pennig and Prof. E. Brug for use with the Long Gamma® Locking Nail.

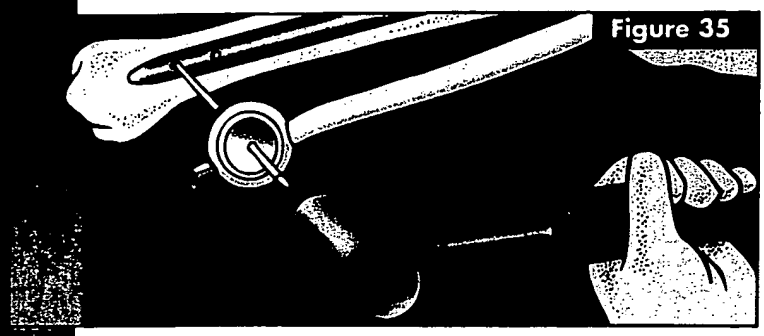


Figure 35

Figure 36

Use the mallet to tap the pin through the near cortex and into the screw hole in the nail – up to *but not into* the far cortex. Hold the targeting device by the handle for greater stability (Figure 35).

Maintain the pin in place and remove the targeting device, then introduce the special drill guide over the pin and up to the near cortex (Figure 36). Using pliers, or the Jacob's chuck (2), remove the Steinmann pin. Hold the drill guide firmly while the pin is removed.

Use the short **blue** 5.5 mm drill bit (23) to drill through both cortices. Remove the drill guide and drill. Measure using the depth gauge, which has an integral sleeve that should contact the near cortex to give the correct distance, and place a screw of appropriate length in a free-hand fashion. Repeat the steps to target the second hole.

FINAL CHECKING

Check the final position of the implant using the image intensifier in the anterior-posterior and lateral planes (Figures 37a & b). Close the wounds (don't forget the small stab wound) with one drain proximally.

POSTOPERATIVE CARE AND REHABILITATION

After the wound is closed, elastic bandage is applied from the toes to the hip. Active and passive mobilization of the lower limbs should be started immediately. The injured limb is kept elevated. The drain is removed when the drainage stops and usually within the first 48 hours. Walking can be started on the third day.

For stable fractures with dynamic locking, full weight-bearing walking can be started immediately.

For unstable fractures with static locking, immediate full weight-bearing walking is allowed in fractures with good bone contact.

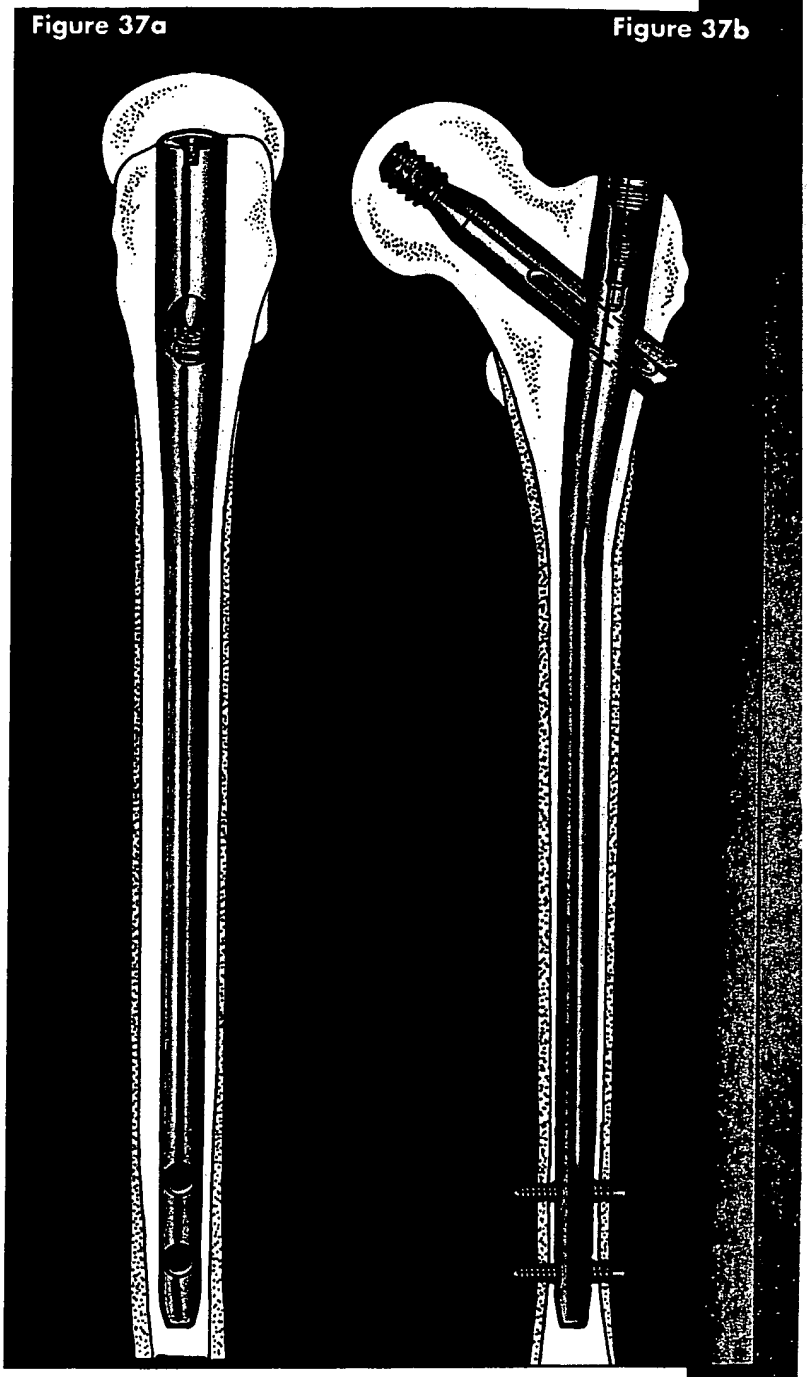
For fractures with poor bone contact due to comminution and large medial third fragment, partial weight-bearing walking is allowed for the first 6 to 8 weeks. Full weight-bearing walking can be commenced when there is a bridging callus formed on the medial side as evident on the follow up X-ray.

Dynamization of the fracture may be performed if delayed union is noted between four and six months after operation.

If the implants are going to be removed after the fracture is healed, removal of the distal locking screw (dynamization) six months prior to implant removal is recommended in order to further improve the quality of the medial cortical bone.

Figure 37a

Figure 37b



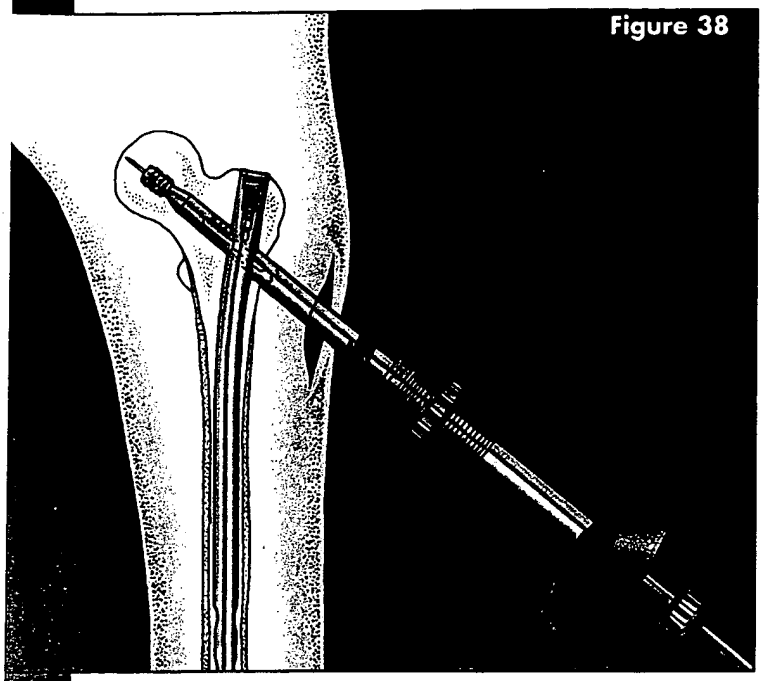


Figure 38

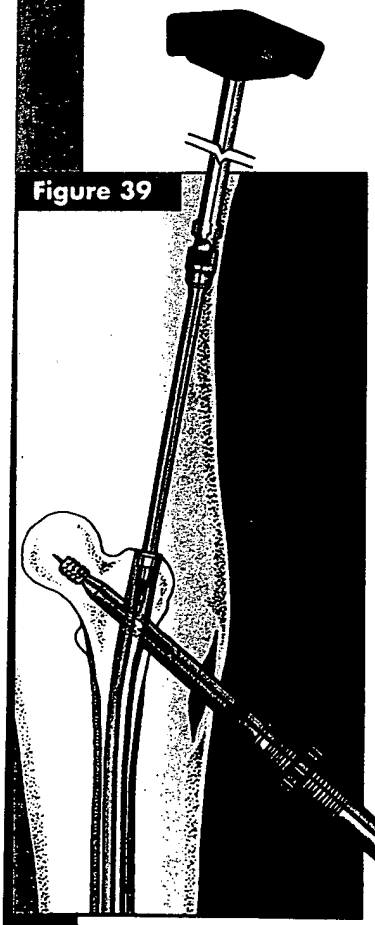


Figure 39

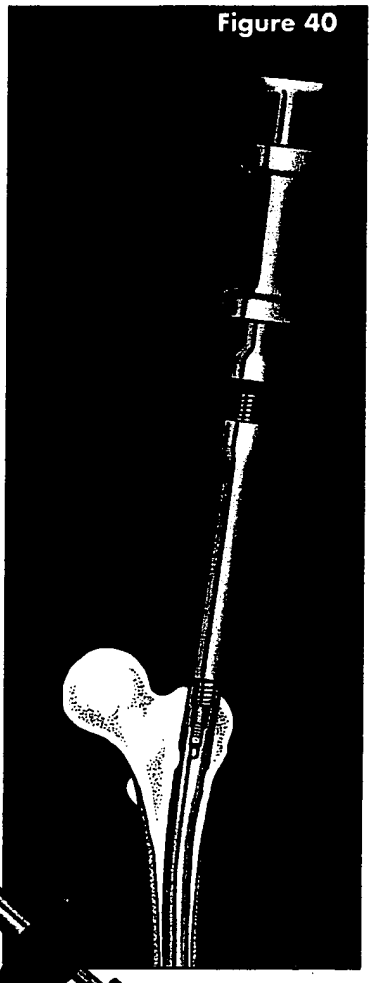


Figure 40

EXTRACTION OF THE LONG GAMMA® LOCKING NAIL

Where extraction is indicated, please proceed as follows:

Step I

Remove the distal screws if fitted.

Step II

Make a small incision through the old scar below the greater trochanter to expose the outer end of the lag screw.

Remove any bony ingrowth which may be obstructing the outer end or internal thread of the lag screw as necessary to ensure correct connection for the lag screwdriver (17)

The lag screw guide wire (13) is then passed up to the lag screw into the head of the femur. The lag screwdriver (17) is passed over the guide wire, using the guide sleeve (11) as a tissue protector, and engaged with the distal end of the lag screw (Figure 38).

Check that ingrowth does not obstruct secure engagement of the lag screwdriver (17), otherwise the lag screw or driver may be damaged and extraction made much more difficult.

Step III

An incision is made over the proximal tip of the nail, the proximal plug is removed, and the set screwdriver (18) is engaged with the set screw. The screw is rotated anticlockwise with the socket wrench (7) far enough to disengage it from the lag screw groove (Figure 39). The set screw does not need to be completely extracted.

Step IV

The lag screw is extracted by rotating the lag screwdriver (17) in an anticlockwise direction. The lag screw guide wire (13) must then be removed.

Step V

Reset set screw to its fully seated position. The nail extraction rod (26) is then threaded into the proximal end of the nail (Figure 40). A sliding hammer assembly (from the G & K system) is attached and the nail extracted. Finally the wounds are closed.

PROBLEM SOLVING

Resistance to nail insertion

Sometimes it is difficult to introduce the nail far enough into the femur. In the case below (Figure 41), the lower end of the nail is impinging on the anterior cortex of the femur.

DO NOT hammer the targeting device (5). Some femurs are highly curved anteriorly and hammering will break the anterior cortex or the base of the greater trochanter.

The cortex should be reamed again using a 13 mm reamer and the nail re-introduced (Figure 42).

If the nail will not go into the femoral cavity far enough to allow correct positioning of the lag screw, further reaming should be carried out in 0.5 mm increments until the nail will go in fully.

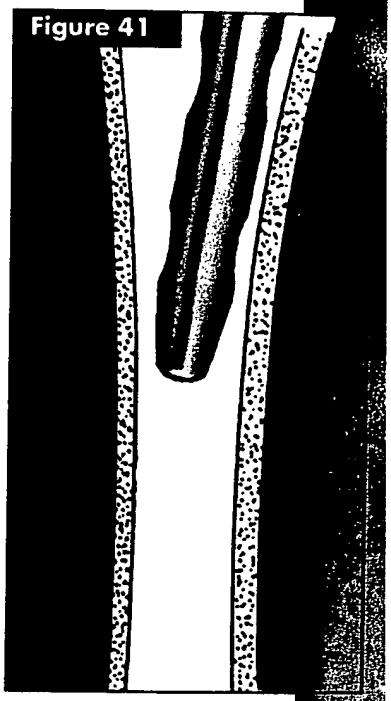


Figure 41

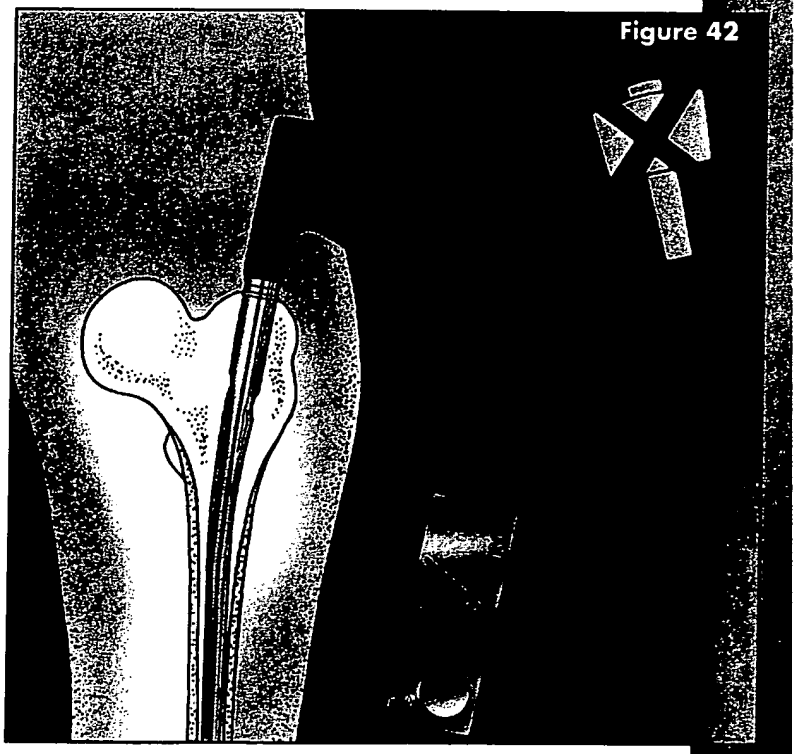


Figure 42

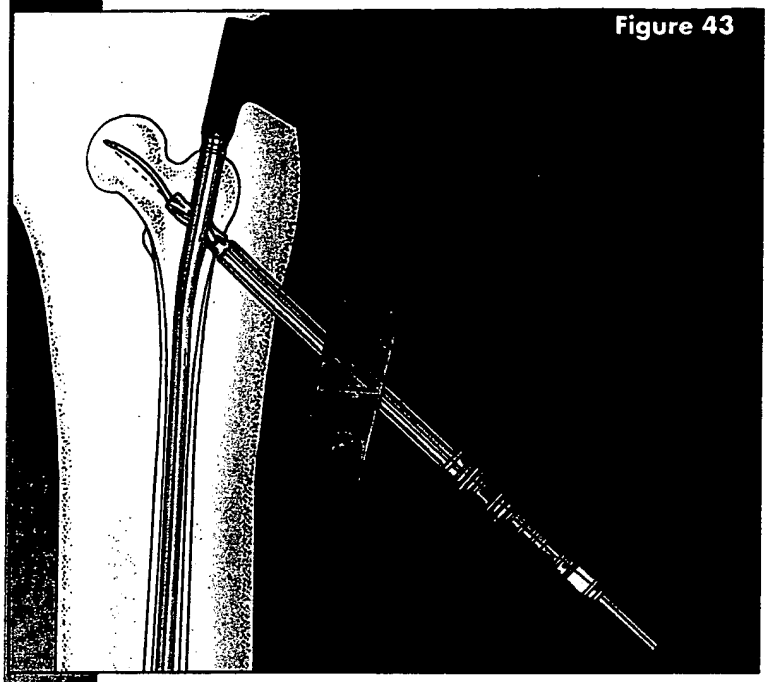


Figure 43

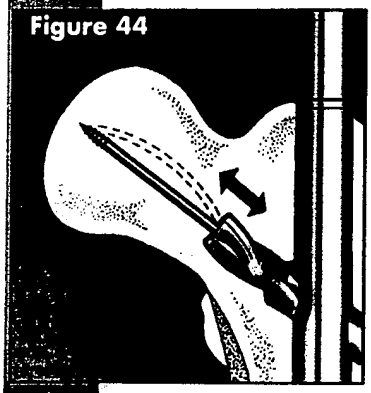


Figure 44

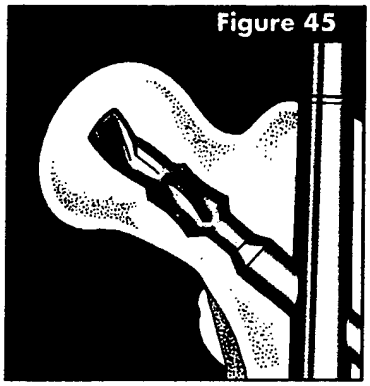


Figure 45

Bent guide wire

If insertion of the guide wire (13) is repeated in order to get a satisfactory position, the wire may be bent due to its passing through a previous track. This makes it difficult to pass the step drill (15) over the bent wire (Figure 43).

If the guide wire (13) is only slightly bent then the step drill (15) can be passed over it using a to and fro movement (Figure 44).

If the guide wire (13) is markedly bent, it should be removed and a new guide wire inserted; alternatively, the step drill (15) can be passed smoothly up to the sub-chondral bone without wire (Figure 45).

Posterior displacement

In the case of a comminuted fracture, there is a tendency for the fracture to become displaced posteriorly, making it difficult to pass the guide wire (13) into the center of the neck or head. This should be solved by lifting the nail insertion targeting device (5).

Alternatively, the assistant could lift the greater trochanter up with his hand, and support it with a sandbag. This will maintain the neck and the femur in nearly the same axis, so that it will be easy to pass the guide wire (13) through the center of the neck and head (Figures 46a, b, c). The position should then be checked on both anterior-posterior and lateral views using the image intensifier. Care is required to avoid radiation risk to the assistant

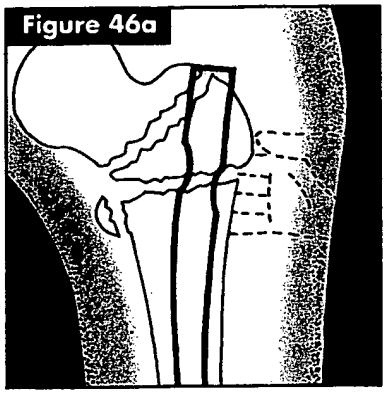


Figure 46a

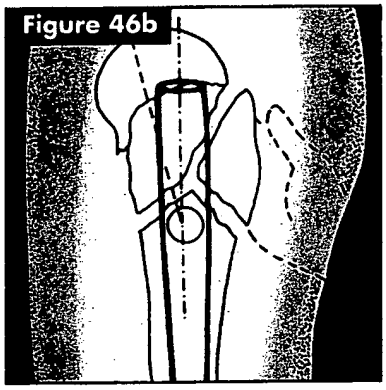


Figure 46b

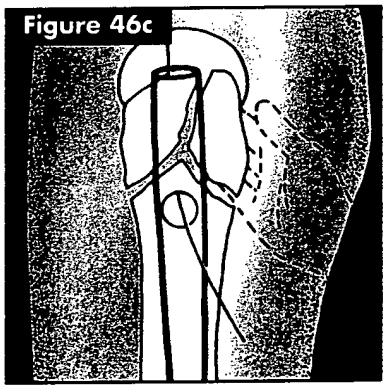


Figure 46c

NOTES

Long Gamma® Locking Nail – Implants

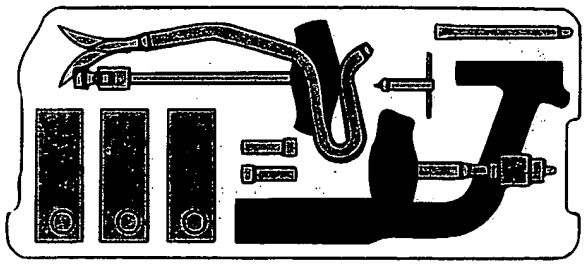
CAT. NO.	DESCRIPTION	SIZE
3370 - 2 - 080	Lag Screw	80 mm
3370 - 2 - 085	Lag Screw	85 mm
3370 - 2 - 090	Lag Screw	90 mm
3370 - 2 - 095	Lag Screw	95 mm
3370 - 2 - 100	Lag Screw	100 mm
3370 - 2 - 105	Lag Screw	105 mm
3370 - 2 - 110	Lag Screw	110 mm
3370 - 2 - 120	Lag Screw	120 mm
3370 - 2 - 130	Lag Screw	130 mm
3370 - 5 - 025	Distal Screw	25 mm
3370 - 5 - 030	Distal Screw	30 mm
3370 - 5 - 035	Distal Screw	35 mm
3370 - 5 - 040	Distal Screw	40 mm
3370 - 5 - 045	Distal Screw	45 mm
3370 - 5 - 050	Distal Screw	50 mm
3370 - 5 - 055	Distal Screw	55 mm
3370 - 5 - 060	Distal Screw	60 mm
3370 - 5 - 065	Distal Screw	65 mm
3370 - 5 - 070	Distal Screw	70 mm
3370 - 5 - 075	Distal Screw	75 mm
3370 - 5 - 080	Distal Screw	80 mm
3370 - 5 - 085	Distal Screw	85 mm
3370 - 5 - 090	Distal Screw	90 mm
3370 - 1 - 000	Set Screw	8x27mm
3370 - 1 - 060	Proximal Plug	

CAT. NO.	DESCRIPTION	SIZE
3370 - 6 - 025	Long Gamma Nail	340 mm x 125° Left
3370 - 6 - 125	Long Gamma Nail	360 mm x 125° Left
3370 - 6 - 225	Long Gamma Nail	380 mm x 125° Left
3370 - 6 - 325	Long Gamma Nail	400 mm x 125° Left
3370 - 6 - 425	Long Gamma Nail	420 mm x 125° Left
3370 - 6 - 525	Long Gamma Nail	440 mm x 125° Left
3370 - 7 - 025	Long Gamma Nail	340 mm x 125° Right
3370 - 7 - 125	Long Gamma Nail	360 mm x 125° Right
3370 - 7 - 225	Long Gamma Nail	380 mm x 125° Right
3370 - 7 - 325	Long Gamma Nail	400 mm x 125° Right
3370 - 7 - 425	Long Gamma Nail	420 mm x 125° Right
3370 - 7 - 525	Long Gamma Nail	440 mm x 125° Right

CAT. NO.	DESCRIPTION	SIZE
3370-6-030	Long Gamma Nail	340 mm x 130° Left
3370-6-130	Long Gamma Nail	360 mm x 130° Left
3370-6-230	Long Gamma Nail	380 mm x 130° Left
3370-6-330	Long Gamma Nail	400 mm x 130° Left
3370-6-430	Long Gamma Nail	420 mm x 130° Left
3370-6-530	Long Gamma Nail	440 mm x 130° Left
3370-7-030	Long Gamma Nail	340 mm x 130° Right
3370-7-130	Long Gamma Nail	360 mm x 130° Right
3370-7-230	Long Gamma Nail	380 mm x 130° Right
3370-7-330	Long Gamma Nail	400 mm x 130° Right
3370-7-430	Long Gamma Nail	420 mm x 130° Right
3370-7-530	Long Gamma Nail	440 mm x 130° Right

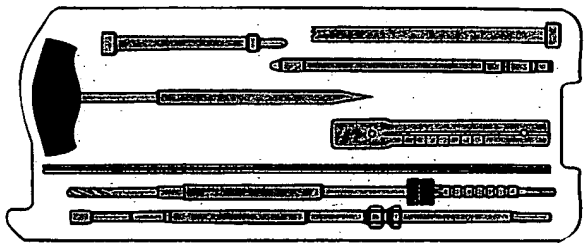
CAT. NO.	DESCRIPTION	SIZE
3370-6-035	Long Gamma Nail	340 mm x 135° Left
3370-6-135	Long Gamma Nail	360 mm x 135° Left
3370-6-235	Long Gamma Nail	380 mm x 135° Left
3370-6-335	Long Gamma Nail	400 mm x 135° Left
3370-6-435	Long Gamma Nail	420 mm x 135° Left
3370-6-535	Long Gamma Nail	440 mm x 135° Left
3370-7-035	Long Gamma Nail	340 mm x 135° Right
3370-7-135	Long Gamma Nail	360 mm x 135° Right
3370-7-235	Long Gamma Nail	380 mm x 135° Right
3370-7-335	Long Gamma Nail	400 mm x 135° Right
3370-7-435	Long Gamma Nail	420 mm x 135° Right
3370-7-535	Long Gamma Nail	440 mm x 135° Right

NOTE: All implants are packaged sterile, 1 unit per package



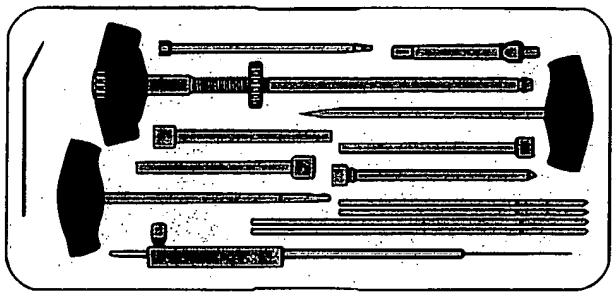
Gamma® Locking Nail Instruments – Top Tray

CAT. NO.	DESCRIPTION
3558 - 9005	Reverse curved awl
	OR
3558 - 9003	Curved awl
1213 - 1300	Socket wrench
1213 - 1100	Nail holding bolt
1213 - 1000	Carbon fiber targeting device
1213 - 1220	Screwdriver for nail holding bolt
1213 - 7000	Jacob's chuck & key
1215 - 2125	Targeting sleeve 125°
1215 - 2130	Targeting sleeve 130°
1215 - 2135	Targeting sleeve 135°



Gamma® Locking Nail Instruments – Middle Tray

CAT. NO.	DESCRIPTION
1214 - 9000	Final Impactor
1210 - 3220	Lag screw guide sleeve
1210 - 5250	Kirschner wire guide sleeve
1213 - 4300	Lag screw awl
1210 - 6450	Kirschner wire 3.2 x 450 mm
1210 - 7190	Lag screw length gauge
1210 - 8100	Lag screw step drill
3371 - 1085	Lag screw tap



Gamma® Locking Nail
Instruments – Bottom Tray

CAT. NO.	DESCRIPTION
1213 - 9000	Lag screwdriver
1213 - 1304	Set screwdriver bit SW4
1214 - 1160	Distal tissue protector 9.0 mm
1214 - 2180	Distal obturator
1214 - 4172	Drill guide sleeve 5.5 mm
1214 - 3265	Distal awl
1214 - 5055	Long Distal drill – 5.5 mm x 300 mm
1214 - 5180	Short Distal drill – 5.5 mm x 220 mm
1214 - 6000	Screw gauge
1214 - 7025	Distal screwdriver SW5
1212 - 1000	Small extraction rod
3251 - 7140	Skin Protector

Not in storage case –

3371 - 1015	3.0 mm blunt tip guide wire, packaged sterile, one unit per package

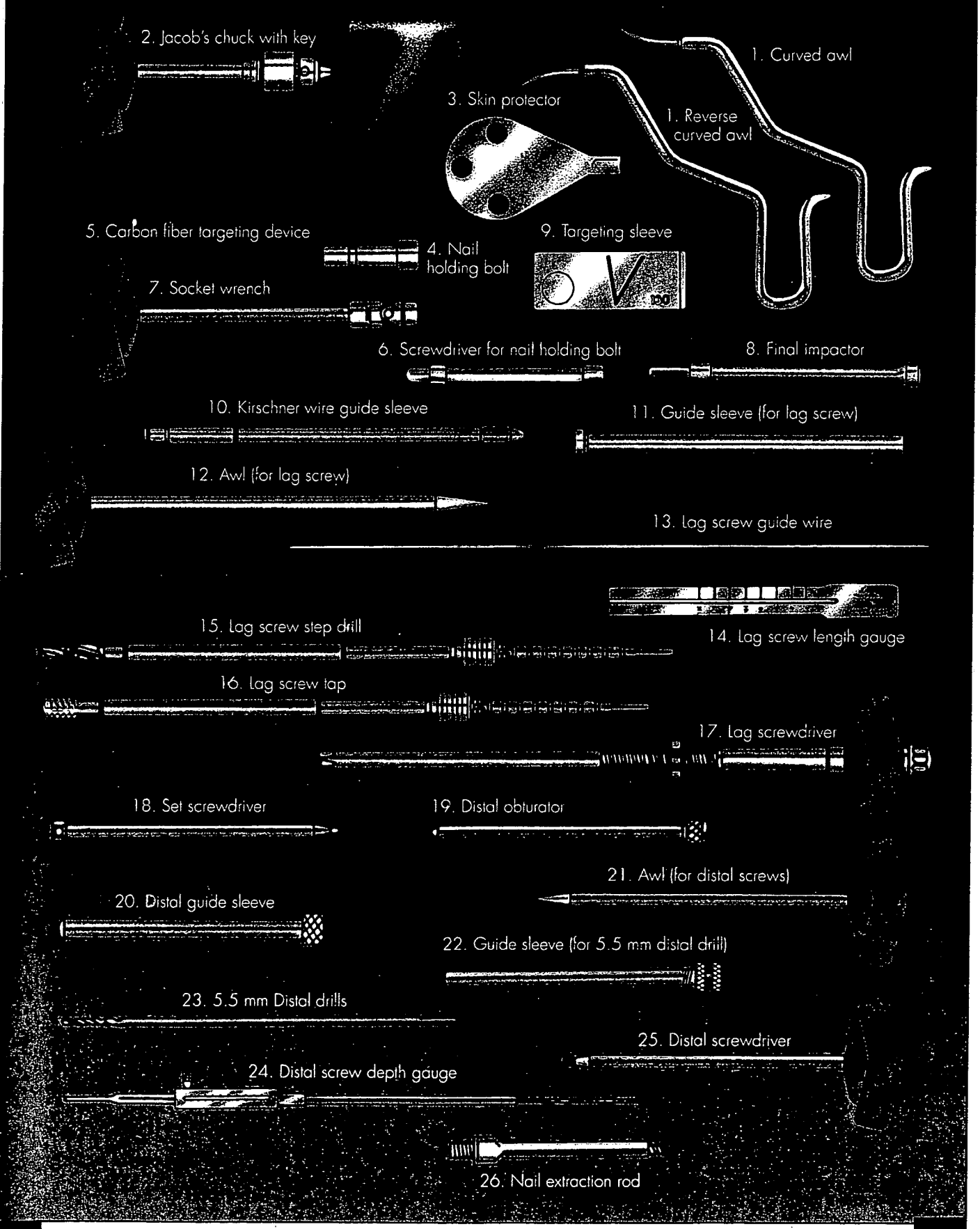
Optional instruments

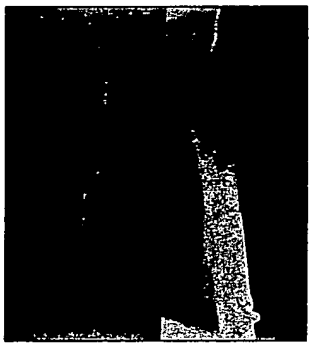
0111 - 5000	Repositioning device
1130 - 2102	Universal Freehand targeting device
1130 - 2110	Steinman pin for freehand targeting device
1130 - 2122	Sleeve for Steinman pin
6809 - 0001	Hammer for Steinman pin

Gamma® Locking Nail
Instrument Storage and sterilization case

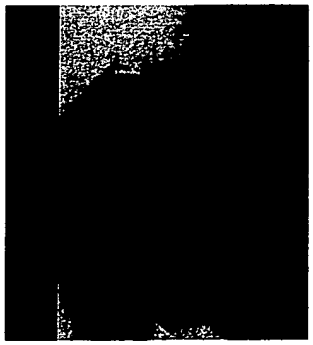
CAT. NO.	DESCRIPTION
3371 - 1190	Storage & sterilization case – empty

INSTRUMENT GUIDE

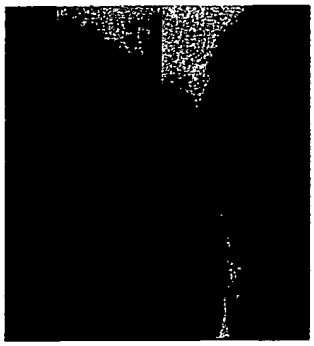




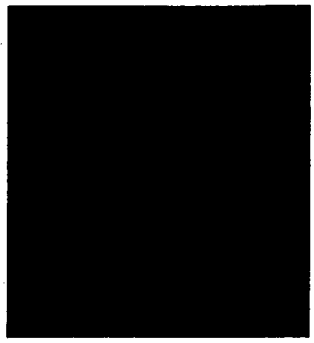
Extended subtrochanteric fracture



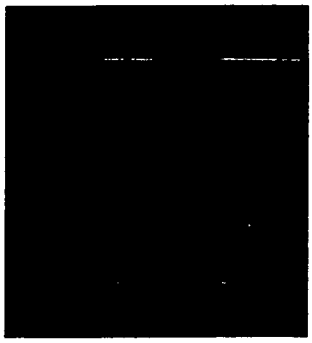
Reduction



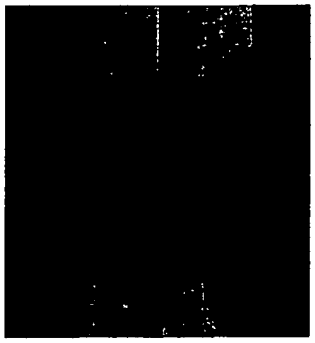
7 months post operation



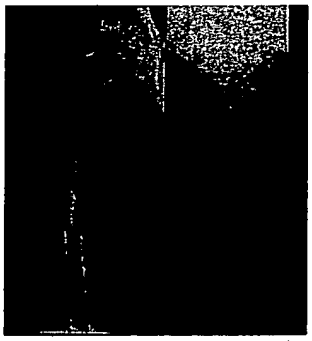
Combined intertrochanteric and shaft fracture



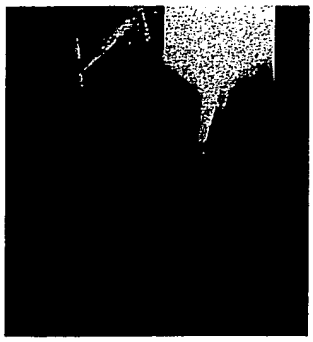
Reduction



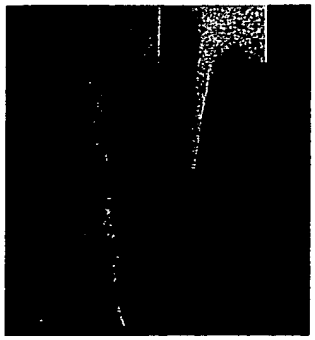
2 months post operation



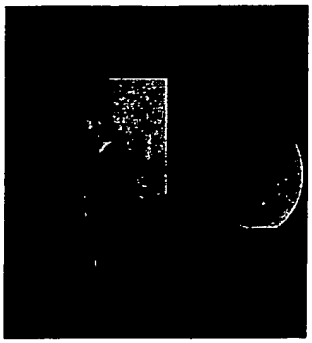
Spinal fracture



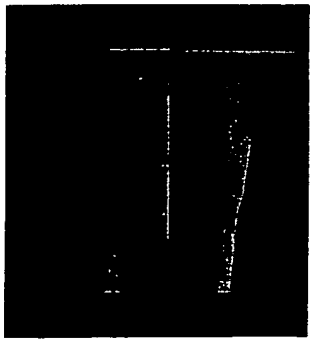
Nail inserted



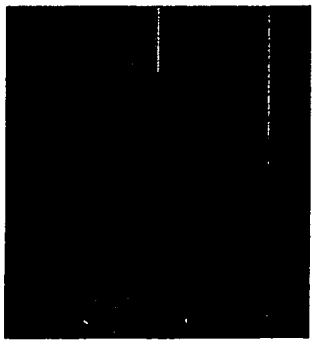
8 months post operation



Pathological fracture



Proximal fixation



Full length fixation

All X-ray photographs by courtesy of Dr. G. Taglang, Centre de Traumatolgie et d'Orthopédie, Strasbourg, France.

Fold out this page to show instrument guide for operating technique.

LONG GAMMA® LOCKING NAIL

stryker
Howmedica
OSTEONICS

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Allendale, NJ 07401

LLGNST 10M 6/99 11071 BC/HAT